Exhibit A

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PUBLIC PENSION FUND GROUP, Plaintiff, v. KV PHARMACEUTICAL COMPANY, MARC S. HERMELIN, DAVID A. VAN VLIET, and RITA E. BLESER, Defendants.	)	No. 4:08-CV1859 (CEJ) JURY TRIAL DEMANDED SECOND CONSOLIDATED AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS CLASS ACTION

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Court-appointed Lead Plaintiffs, the Norfolk County Retirement System and the State-Boston Retirement System (collectively, "Lead Plaintiffs"), allege the following based upon the investigation of Lead Counsel, which included review of the filings by KV Pharmaceutical Company ("KV" or the "Company") with the United States Securities and Exchange Commission ("SEC"); administrative agency documents, including documents from the Food and Drug Administration ("FDA"); additional regulatory filings and reports; public judicial records; securities analysts' reports and advisories; and press releases and media reports. Lead Plaintiffs believe that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. Lead Plaintiffs bring this action for violations of the federal securities laws on behalf of all purchasers of KV publicly traded securities between June 15, 2004 and January 23, 2009 (inclusive) (the "Class Period"), who were damaged thereby, with certain exceptions that are noted below (the "Class").

2. This case is the result of KV's systematic and continuous violations of FDA regulations in manufacturing pharmaceutical products over the last nine years despite repeated warnings by FDA to the Company's most senior executives. The foreseeable risk of Defendants' intentional disregard of FDA's warnings included the complete shutdown of the Company's manufacturing activities, which ultimately occurred on January 23, 2009.

3. The first inkling of the Company's impending shutdown came on August 11, 2008, when KV disclosed that the Audit Committee of its Board of Directors had commenced an independent investigation into allegations of management misconduct. Management reported the inquiry as part of its quarterly earnings report, and sought to downplay its significance by

saying that it did not believe that there had been any misconduct that would have a material financial impact.

4. When KV announced its next quarter's earnings on November 12, 2008, however, the Company admitted that the scope and seriousness of the investigation had expanded considerably. Legal counsel, including FDA regulatory counsel, and other advisers had been summoned to "assist" in the inquiry. Two products had been recalled only days before as a result of the probe. The allegations had grown and now arose "from multiple sources." And most importantly, the management misconduct at issue was now identified to concern FDA regulatory and other compliance matters.

5. Nearly three weeks later, on December 5, 2008, the Company terminated its Chief Executive Officer, Marc S. Hermelin ("Hermelin"), for cause, as a result of the investigation. Dismissal for cause under Defendant Hermelin's employment agreement required improper conduct "with full knowledge of all pertinent facts." Defendant Hermelin's departure was even more shocking because he owned a controlling block of the common stock, more than 66% of the Class B shares which had super voting rights over the Class A shares owned by the public at large. Defendant Hermelin's father also had founded the Company in 1942, and they had been the only two CEO's to this point.

6. On December 23, 2008, KV then announced that it was suspending all manufacturing and distribution of pharmaceutical products in tablet form. This represented $159 million of net revenues in fiscal 2008, or more than 25% of total revenues. KV was also forced to admit that this would have a material adverse effect on its financial results. A month later, on January 26, 2009, the Company suspended all manufacturing activities and recalled most of its

products. It also disclosed that FDA's Office of Criminal Investigations ("OCI") had begun participating in the investigation.

7. As a result of this wave of disastrous revelations, and potential criminal liability, KV's stock price for Class A shares collapsed from more than $30 at the height of the Class Period, to 51 cents at the close of trading on January 26, 2009. Investors lost approximately $1.5 billion in market capitalization.

8. KV's knowledge of the repeated and intentional disregard of FDA regulations extended to the highest levels. On March 2, 2009, FDA filed a Complaint for Permanent Injunction (the "FDA Complaint" or "FDA Action") naming as defendants all the Defendants in this Action, as well as others not named here.[1] The suit was based on FDA's most recent inspection conducted between December 15, 2008 and February 2, 2009. The inspection found that KV had failed to rectify for years the "same" or "similar" violations that FDA had observed and instructed KV to correct:

> Defendants' noncompliance has continued despite repeated warnings from FDA regarding its cGMP [current Good Manufacturing Practices] violations. At the conclusion of each FDA inspection in 4/2003, 1/2004, 1/2005, 3/2006, 4/2007, 3/2008, 8/2008 and 2/2009, FDA investigators prepared and issued a detailed List of Inspectional Observations, Form FDA-483, to Defendants, notifying them of the investigators' observations. **The FDA investigators discussed the violations listed in the Form FDA-483s with Defendants**, **who expressed a desire to correct the deficiencies**. Nevertheless, FDA investigators have continued to observe cGMP violations at subsequent inspections. (Exhibit 1, FDA Cmpt. at ¶¶ 23-24) (emphasis supplied).

9. Rather than attend to the violations and seek to cure them, KV further expanded its production and manufacturing practices by embarking on the most important and largest

[1] United States of America v. KV Pharmaceutical Company et al., Eastern District of Missouri, No. 09-334 (RWS).

launch of a brand new product in its history. To much fanfare, throughout 2007 and early-2008, KV prepared to launch a generic version of Toprol XL, Metoprolol Succinate Extended Release Tablets ("Generic Metoprolol"), a cardiovascular drug. The Company had millions in earnings riding on this, as well as its stock price.

10. KV launched Generic Metoprolol in the Summer of 2007 and sold more than $100 million within the first year. Unbeknownst to investors and patients, however, FDA subsequently determined in 2009 that Generic Metoprolol was not "developed in a scientifically sound manner," and that "all strengths have historically resulted in drug product of variable quality."

11. The launch of Generic Metoprolol highlights Defendants' thirst for profits and contempt for FDA regulations. This is not only reprehensible in its own right, but more so in light of the injuries suffered by those who ingested KV's defective drugs. The Company has reported that at least three wrongful death lawsuits have been filed since last fall due to morphine sulfate pills with excessive dosage. Multiple other lawsuits allege personal injury, short of death. And all this, despite the fact that, according to FDA, the Company had received almost one-thousand complaints in 2007 and 2008 with respect to a KV prenatal vitamin product, and over forty adverse event reports reflecting negative medical reactions. The Company had ample warning about its manufacturing deficiencies prior to the shutdown.

12. Finally, on February 25, 2010, KV announced that the Company's largest subsidiary, ETHEX, would plead guilty to two felony counts of criminally violating the Federal Food, Drug, and Cosmetic Act (the "FDCA"). The United States filed an Information with this District Court in connection with the criminal violations on March 2, 2010. According to the Information, the felony violations arise out of ETHEX's "intent to defraud and mislead" by

failing to report to the FDA that certain drugs had been manufactured defectively and failed to meet product specifications.

13. As the Company tries to comply with FDA regulations in order to resume operations, this dark and sordid chapter in KV's history continues to unfold – a chapter in which, as set forth below, KV made false and misleading statements and failed to disclose the foreseeable risk that its known – yet undisclosed – FDA violations would cause a complete shutdown of the Company's manufacturing operations.

II. JURISDICTION AND VENUE

14. The claims asserted arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. §240.10b-5, promulgated thereunder. Jurisdiction is conferred by §27 of the Exchange Act, 15 U.S.C. §78aa.

15. Venue is proper here pursuant to Section 27 of the Exchange Act because KV maintains its principal executive offices in this District.

III. THE PARTIES

16. Court-appointed Lead Plaintiff Norfolk County Retirement System ("Norfolk") is the pension plan for the public employees of Norfolk County, Massachusetts. It currently has approximately $450 million in assets and over 9,500 active and retired members. Norfolk County consists of twenty-eight eastern Massachusetts communities, mostly located to the south and west of Boston. Norfolk purchased KV securities during the Class Period as set forth in the attached certification which is incorporated herein by reference, and was damaged thereby.

17. Court-appointed Lead Plaintiff State-Boston Retirement System ("Boston") is the pension plan for the public employees of the City of Boston. Boston has approximately $3.1 billion in assets, and more than 34,000 active and retired members. Boston purchased KV

securities during the Class Period as set forth in the attached certification which is incorporated herein by reference, and was damaged thereby.

18. Defendant KV is a pharmaceutical company with offices at 2503 South Hanley Road, St. Louis, Missouri.

19. Defendant Hermelin served as Vice-Chairman of the Board of Directors and Chief Executive Officer of the Company from 1975 until August 2006. In August 2006, Defendant Hermelin became Chairman of the Board of Directors, in addition to Chief Executive Officer, and continued in both positions until December 5, 2008, when he was terminated for cause. Defendant Hermelin remains a member of the Company's Board of Directors.

20. Defendant Hermelin, because of his position with the Company and substantial ownership of Class B Shares and controlling block of stock (as detailed below), possessed the power and authority to control the Company's actions and the content of KV's public disclosures. Defendant Hermelin signed all the Forms 10-K and 10-Q filed with the SEC during the Class Period, was provided with copies of the Company's reports and public disclosures alleged herein to be false and misleading prior to their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his position, stock ownership, and access to material non-public information, Defendant Hermelin knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the representations which were being made were materially false and misleading.

21. Defendant David A. Van Vliet ("Van Vliet") has been KV's Chief Executive Officer since December 2, 2009. Van Vliet served as the Corporate President and interim Chief Executive Officer of the Company between December 5, 2008 and December 2, 2009. Previously, Defendant Van Vliet served as Chief Administration Officer beginning in September

2006 until September 5, 2008, when he was appointed President and Chief Executive Officer of the ETHEX Corporation, the largest subsidiary of the Company. At all times since September 2006, Defendant Van Vliet has been an executive officer of the Company. Defendant Van Vliet is only being sued for his actions, or failure to act, since September 2006, the beginning of his employment as Chief Administration Officer with the Company, and not for any of his statements, actions, or conduct before September 2006.

22. Because of Defendant Van Vliet's position and access to material non-public information available to him, but not the public, Defendant Van Vliet knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public and that the representations which were being made were then materially false and misleading. Defendant Van Vliet's knowledge and participation in discussions with FDA regarding the Company's continued violations of FDA regulations and cGMP throughout the Class Period, and the concealment of and failure to disclose to the public those discussions and violations during the Class Period, constituted (i) a manipulative or deceptive device or contrivance, (ii) a device, scheme or artifice to defraud, and (iii) an act, practice, or course of business which operated or would operate as a fraud or deceit upon investors in connection with the purchase or sale of KV securities.

23. Defendant Rita E. Bleser ("Bleser") has been the President of KV's Pharmaceutical Manufacturing Division since April 2007 and an executive officer of the Company. Defendant Bleser is only being sued for her actions, or failure to act, since April 2007, the beginning of her employment with the Company, and not for any of her statements, actions, or conduct before April 2007.

24. Because of Defendant Bleser's position and access to material non-public information available to her, but not the public, Defendant Bleser knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public and that the representations which were being made were then materially false and misleading. Defendant Bleser's knowledge and participation in discussions with FDA regarding the Company's continued violations of FDA regulations and cGMP throughout the Class Period, and the concealment of and failure to disclose to the public those discussions and violations during the Class Period, constituted (i) a manipulative or deceptive device or contrivance, (ii) a device, scheme or artifice to defraud, and (iii) an act, practice, or course of business which operated or would operate as a fraud or deceit upon investors in connection with the purchase or sale of KV securities.

25. Defendants Hermelin, Van Vliet and Bleser are referred to herein, collectively, as the Individual Defendants.

IV. SUBSTANTIVE ALLEGATIONS

A. BACKGROUND ON KV PHARMACEUTICAL

26. KV is a pharmaceutical company that develops, manufactures, and markets prescription drugs. The Company has three operating segments: generic products, branded products, and specialty raw materials. Each segment is marketed by one of the Company's three principal subsidiaries, ETHEX, Ther-Rx, and Particle Dynamics, Inc., respectively.

27. ETHEX, the Company's generic division, offered more than 130 products in four major categories: cardiovascular, women's health, pain management, and respiratory/cough/cold. ETHEX also marketed over 40 products in the gastrointestinal, dermatological, and general nutritional categories. ETHEX accounted for about 60% of the Company's net revenues during the Class Period.

28. Ther-Rx competes in the branded prescription pharmaceutical segment. Ther-Rx has introduced 14 products in three specialty therapeutic categories: cardiovascular, women's health, and oral hematinics. Ther-Rx accounted for about 35% of the Company's net revenues during the Class Period.

29. Particle Dynamics develops and markets specialty raw materials for the pharmaceutical, nutritional, food, and personal-care industries, and accounted for approximately 5% of the Company's net revenues during the Class Period.

30. The Company has two classes of voting stock, Class A ("Class A Shares") and Class B ("Class B Shares") (collectively, "Common Stock"). As set forth in the Proxy Statement dated July 29, 2008, there were 37,767,037 Class A Shares outstanding and 12,163,482 Class B Shares outstanding. Class B Shares have, what is commonly referred to as, super voting rights – each Class B Share has twenty votes per each Class A Share vote.

31. In addition, as of July 29, 2008, the Company had 40,000 shares of 7% Preferred Stock issued and outstanding (the "Preferreds"). Each share of the Preferreds is convertible into Class A Shares at a ratio of 8.4375 Class A Shares for each share of the Preferreds. Together with the Common Stock, the Preferreds constitute all of KV's publicly traded securities during the Class Period.

32. Defendant Hermelin has a controlling majority of the Company because he controls 10.5% of the Class A Shares and 66% of the Class B Shares.

B. FDA COMPLAINT FOR A PERMANENT INJUNCTION

33. On March 2, 2009, the United States filed a Complaint for Permanent Injunction in this Court (the "FDA Complaint") (attached as Exhibit 1) against the Company, ETHEX, Ther-Rx, Defendants Hermelin, Van Vliet, and Bleser, as well as against another senior executive, Jay S. Sawardeker (collectively, the "FDA Defendants"). The FDA Complaint sought

to permanently enjoin and restrain the Company and any of its agents from manufacturing, processing, packing, labeling, holding or distributing any article of drug. (Exhibit 1, FDA Cmpt. at 8). The lawsuit was the result of an inspection of KV's manufacturing facilities by FDA between December 15, 2008 and February 2, 2009 (the "2009 Inspection").

34. The 2009 Inspection established that the Company had been violating FDA regulations and failed to conform with current Good Manufacturing Practices ("cGMP") since at least 2000. (Exhibit 1, FDA Cmpt. at ¶ 25). Defendants in the FDA Action, which includes all defendants here, have known since at least April 2003 of these violations and had discussions with the FDA throughout this period regarding the violations. (Exhibit 1, FDA Cmpt. at ¶ 24). The specific list of violations includes a plethora of illegal activity.

1. KV Sold Adulterated Drugs

35. According to the FDA Complaint, the 2009 Inspection "established" that the drugs manufactured by KV were adulterated within the meaning of the FDCA. (Exhibit 1, FDA Cmpt. at ¶ 13). In other words, KV's manufacturing, processing, packing, labeling, holding and distribution of drugs were not in compliance with cGMP. *Id.*

36. FDA investigators also documented thirty-five separate violations of cGMP, all set forth in a Form FDA-483. (Exhibit 1, FDA Cmpt. at ¶ 15). These violations of the FDCA included the:

(a) Failure to follow the responsibilities and procedures applicable to the quality control unit;

(b) Failure to establish control procedures to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process materials and the drug product;

(c) Failure to make written records of investigations into unexplained discrepancies and the failure to make written records of investigations of a batch or any of its components to meet specifications;

(d) Failure to review and approve drug product production and control records by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed;

(e) Failure to review and approve changes to written procedures by the quality control unit;

(f) Failure to clean, maintain, and sanitize equipment and utensils at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product; and

(g) Failure to follow written production and process control procedures in the execution of production and process control functions. (Exhibit 1, FDA Cmpt. at ¶ 15).

2. KV Sold Unapproved And Misbranded Drugs

37. The 2009 Inspection also revealed that KV manufactured and distributed drugs that lacked new drug applications ("NDAs") or Abbreviated New Drug Applications ("ANDAs"), and that were not exempt from the FDCA's pre-market approval requirements. (Exhibit 1, FDA Cmpt. at ¶ 18). Accordingly, these drugs were unapproved new drugs in violation of the FDCA.

38. By failing to properly file (or obtain proper approval of its) NDAs and ANDAs for the drugs manufactured and distributed into the market, KV also effectively misbranded these drugs. FDA regulations require that drugs be labeled precisely pursuant to the approval of the NDA or ANDA. Failure to obtain that approval establishes that the labeling constitutes misbranding in violation of the FDCA. (Exhibit 1, FDA Cmpt. at ¶¶ 20-22).

3. The FDA Defendants Knew Since Early 2003 That KV Sold Adulterated And Unapproved Drugs In Violation of FDA Regulations

39. The FDA Complaint establishes that the FDA Defendants knew, since at least early-2003, that KV was in violation of numerous FDA regulations. (Exhibit 1, FDA Cmpt. at ¶¶ 23-27). Many of the violations found during the 2009 Inspection were the "same as, or similar to," the violations first identified in early-2003, but which KV never rectified, even after multiple follow-up inspections. According to the FDA Complaint:

> Defendant KV Pharmaceutical Company has a history of continuing cGMP violations. **The deficiencies observed by the FDA at the most recent inspection in February 2009, are the same as, or similar to, prior violations observed by FDA at several other inspections conducted during the last eight years**.
>
> Defendant's noncompliance has continued despite repeated warnings from FDA regarding its cGMP violations. At the conclusion of each FDA inspection in 4/2003, 1/2004, 1/2005, 3/2006, 4/2007, 3/2008, 8/2008 and 2/2009, FDA investigators prepared and issued a detailed List of Inspectional Observations, Form FDA-483, to Defendants, notifying them of the investigators' observations. **The FDA investigators discussed the violations listed in the Form FDA-483s with Defendants**, who expressed a desire to correct the deficiencies. Nevertheless, FDA investigators have continued to observe cGMP violations at subsequent inspections. (Exhibit 1, FDA Cmpt. at ¶¶ 23-24) (emphasis supplied).

40. FDA had also already warned KV that subsequent violations could result in seizure and/or injunction. On May 9, 2000, FDA issued a Warning Letter to KV identifying numerous cGMP violations found during a February and March 2000 inspection. According to the FDA Complaint, the Warning Letter emphasized the serious nature of the violations.

C. THE 2009 INSPECTION DOCUMENTED RAMPANT AND SYSTEMATIC ABUSES OF FDA REGULATIONS

41. As mentioned above, on February 2, 2009, FDA completed its inspection of KV's manufacturing facilities and issued the Company a list of thirty-five "Inspectional Observations"

in a Form FDA-483 ("Form 483") (attached as Exhibit 2). Nine FDA investigators signed the Form 483 which was issued to Defendant Van Vliet as Interim President and Interim CEO.

42. Observation 1 concluded that the "Quality Control/Quality Assurance (QC/QA) functions **have** failed," and that "upper management" gave specific instructions to violate QC/QA procedures (Exhibit 2, Form 483 at 1-2) (emphasis supplied). Upper management's violations concerned KV's most important product in 2007 and 2008, Generic Metoprolol, responsible for the supposed explosive growth in revenues and earnings, and sustained high stock price.

1. KV Was Never Able to Manufacture Generic Metoprolol Safely

43. FDA concluded that KV was never able to properly manufacture Generic Metoprolol, the Company's leading drug:

> It does **not** appear the Metoprolol Succinate ER Tablets product line (25mg, 50mg, 100mg, 200mg) was developed in a scientifically sound manner with appropriate specifications and process controls. All strengths have historically resulted in drug product of variable quality when, the designed processes are executed as evidenced by the high numbers of batch rejects, in-process rejects, out-of-specification (OOS) test results and non-conformance reports (NCRs) at all manufacturing stages. (Exhibit 2, Form 483 at 3) (emphasis supplied).

44. Among the violations, FDA found evidence that KV simply did not follow the "designed process" for manufacturing Generic Metoprolol 100mg tablets. Since August 5, 2007, KV had used an active ingredient that resulted in smaller particle sizes than approved by FDA in the validation study. Yet, KV "continued to manufacture and distribute approximately [redacted] lots of these tablets until October 17, 2008, when [KV] ceased production." (Exhibit 2, Form 483 at 5).

45. Another flagrant violation concerned KV's attempt to resolve dissolution problems caused by lower than target assay values. (Assay values refer to the proportion of

ingredients in a pharmaceutical product). In other words, the ingredients of the drug were out-of-specification ("OOS") and approval parameters. Instead of simply rejecting and discarding these defective units, "upper management" decided to "blend" lots that had low assay values with lots that had target or high assay values. There was no justification, documentation, or, more importantly, approved procedure for this blending. (Exhibit 2, Form 483 at 2).

46. FDA also found evidence that when KV properly identified the dissolution problem, it simply failed to correct it. On August 6, 2008, KV identified "excessive press speed" to be the root cause of the dissolution failures. Yet, KV continued to operate at excessive press speeds after August 6, 2008, and to distribute that product until the 2009 Inspection. (Exhibit 2, Form 483 at 6). The identification of the "excessive press speed" as the root factor causing dissolution also demonstrated that KV's initial validation study was faulty. The supposed "excessive" press speed was within the range of the initial validation study. (Exhibit 2, Form 483 at 6).

47. Additional out-of-specification problems with Generic Metoprolol included, "loss on drying," content uniformity, and particle size. The non-conformance reports included but were not limited to the following: "Foreign Tablet; unapproved deviation; Speed Study; Failed AQL [Acceptable Quality Limit]-broken tablet; Omission of IR [immediate release] Pellets; Expired ER [extended release] Pellets; Content Uniformity; Metal shaving found on [redacted] Press; IR pellet Particle Size; Sample Prep error; and ER pellet particle size." (Exhibit 2, Form 483 at 5).

2. The Production Of All Tablet Products Lacked Acceptable Quality Limit Assessments

48. Acceptable Quality Limit ("AQL") is a procedure designed to statistically sample production defects and set maximum limits of statistically acceptable defects per batch. KV simply failed to do this with respect to drugs manufactured in tablet form:

> [KV has] failed to adequately study causes for the acceptable quality limit (AQL) failures which occur across product lines and include among others, nutritional, Metoprolol Succinate and Morphine family products . . . . Despite changes to manufacturing equipment in tablet coating, product failures continue. **This brings into doubt the validation of this process steps for all coated and quality of products on the market**.
>
> Investigations [by KV] exist which occasionally list upstream manufacturing of core tablet issues as possible causes to coated tablet failures. Some of these encompass hardness, % loss on drying of the granulation, compression speeds and compression force. **None of these issues is [sic] adequately investigated [by KV] to determine the root cause and instead coating is solely blamed with system upgrades**. (Exhibit 2, Form 483 at 7) (emphasis supplied).

49. In other words, KV ignored the tablet failures and sought to paper this willful neglect by purportedly blaming the third-party vendor, yet failing to demand that the third-party vendor rectify the purported problem.

3. KV Failed To Take Action With Respect To PrimaCare One Even Though It Received 980 Complaints and 47 Adverse Event Reports Between 2007 And 2008

50. Another critical drug that evidenced continuous defects was PrimaCare One, a prenatal multivitamin sold in capsule form. KV could not stop the capsules from leaking. The Company received 350 complaints in 2007 and 26 adverse event reports ("ADEs"). ADEs mean that patients suffered a negative medical effect. In 2008, the number of complaints rose to 630 and there were an additional 21 ADEs. (Exhibit 2, Form 483 at 2).

51. The Form 483 thus concluded that "the quality control unit **has failed** to implement adequate corrective and preventative action into the hundreds of complaints of leaking capsules received on PrimaCare One, Prenatal Multivitamin/Mineral Capsules. **[KV] continued distribution of this product despite continued complaints of leaking capsules**." (Exhibit 2, Form 483 at 2) (emphasis supplied).

4. KV Ignored Well-Identified Problems And Continued Manufacturing Defective Hydromorphone HCl Tablets

52. KV also ignored known and required modifications in the manufacturing process of Hydromorphone HCl Tablets ("HCl Tablets") by continuing to produce and distribute defective tablets. In December 2005 and January 2006, several validation batches of HCl Tablets "failed to demonstrate control and reproducibility" because "blend uniformity and potency failures occurred." (Exhibit 2, Form 483 at 6). KV identified the compression process as problematic, made modifications to this process, and validated the new process in June 2006. Then, KV just ignored the new process and reverted back to the old defective procedures that resulted in dangerous drugs. (Exhibit 2, Form 483 at 6).

53. More specifically, the June 2006 validation study had required decreasing the compression speed and using a manual hand-fill process. Until then, KV had used an automatic filler instead of a manual one. But after the June 2006 validation study, KV simply did not revise the manufacturing procedures and continued using the automatic filler between June 2006 and August 2008. (Exhibit 2, Form 483 at 6).

54. FDA also determined, during the 2009 Inspection, that the June 2006 validation study had been flawed. No record existed documenting the number of times the samples were collected to ensure adequacy of compression across the batch. In addition, FDA found

discrepancies in the data for the tablet hardness collected at various hardness levels. (Exhibit 2, Form 483 at 7).

5. Additional Systemic Violations Of cGMP

55. The FDA's Form 483 lists numerous additional violations of FDA rules and cGMP establishing that this was a chronic Company-wide phenomena that affected all product lines.

(a) KV also did not report the production of overfilled capsules until the 2009 Inspection had commenced. The Company found overfilled capsules of Potassium Chloride ER on November 21, 2008, but KV did not report the overfilled capsules until January 6, 2009 (three weeks into the 2009 Inspection). (Exhibit 2, Form 483 at 19).

(b) KV found metal contamination in at least four different products between July 22 and December 24, 2008. KV's investigation failed to determine the exact source and nature of the metal, and even failed to investigate one of the critical raw material suppliers until questioned by FDA during the 2009 Inspection. (Exhibit 2, Form 483 at 19).

(c) KV failed to investigate two consumer complaints due to foreign objects found in capsules of Potassium Chloride. (Exhibit 2, Form 483 at 22).

(d) KV continued to utilize packaging components supplied by a vendor which was disqualified on May 29, 2007. (Exhibit 2, Form 483 at 23).

(e) "Equipment and utensils [were] not cleaned, maintained, and sanitized at appropriate intervals as to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product." (Exhibit 2, Form 483 at 23).

D. DESPITE COMPANY-WIDE MANUFACTURING FAILURES AND LACK OF COMPLIANCE WITH FDA REGULATIONS, KV EMBARKED IN 2007 IN THE LAUNCH OF THE MOST IMPORTANT NEW DRUG IN THE COMPANY'S HISTORY: GENERIC METOPROLOL

1. KV Launched Generic Metoprolol In July 2007

56. The FDA Complaint documented, in ample detail, that by 2007 KV had been violating FDA regulations and cGMP for four years. KV had also been issued Forms FDA-483 in each of those four years for continued and repeated illegal conduct. Yet, KV did not seek to resolve its manufacturing deficiencies. Instead, the Company embarked in the biggest drug release in its history—the launch of Generic Metoprolol.

57. Metoprolol is a selective β1 receptor blocker principally used to treat hypertension. The branded product, Toprol-XL(R) is sold in the United States by AstraZeneca. The patent was originally set to expire in September 2007 but was invalidated by the Federal Circuit on July 26, 2007.

58. Total sales of Toprol-XL(R) in the United States in 2006 were $1.71 billion, with the two most common dosages (100mg and 200mg) accounting for $779.2 million. Total net revenues for KV in 2006 were $368 million. Accordingly, even a moderate percentage of the market for Generic Metoprolol would result in a dramatic increase in net revenues and growth for the Company.

59. In light of the potential windfall, KV fiercely sought to launch the first generic version of the 100mg and 200mg varieties. Once the first generic is distributed into the market, it is extremely difficult for competitors to displace it. As a Wall Street analyst research report on KV by Roth Capital Partners ("Roth") explained on June 15, 2007:

> In the absence of a major underlying factor such as a supply failure, a generic manufacturer's market share is more-or-less "permanent" and subject only to relatively minor fluctuations. This was especially apparent during the launch of [a generic] in

> late November 2006 [by a KV competitor] . . . . The uptake of the generics was extraordinarily rapid, even by current standards, with the generics claiming 61.0% of all dispensed prescriptions in the first full month of launch. By month 6, the generics had claimed a full 80% of the market.

60. Wall Street analysts understood that the launch of Generic Metoprolol constituted a critical event and a strong driver for the stock price. Deutsche Bank issued an analyst report on May 18, 2007, titled "Toprol Finally Approved; Several Rx Launches to Follow," which concluded that "generic Toprol XL [was] an earnings 'breakout' opportunity for KV, with a conservative annual incremental [earnings per share] contribution of $0.50+ during the first year and perhaps $0.20 in year two." Deutsche Bank thus estimated that earnings per share would rise by more than 50%, from $1.04 in fiscal[2] 2007 to $1.64 in fiscal 2008. The report also raised KV's stock price target from $28 to $34 per Class A Share, which was trading at $26.90 at the time.

61. On July 26, 2007, KV announced it had begun shipping 100mg and 200mg strengths of Generic Metoprolol. Defendant Hermelin said: "Today marks a major milestone for our Company. Our entire KV team has worked hard to accomplish this achievement and we look forward to the execution of a successful launch of this product through our outstanding team at ETHEX Corporation."

62. Wall Street research analysts watched the launch closely. On August 14, 2007, Roth issued a research report titled, "Toprol-XL generic Launch Going Well." The report observed that "KV achieve[d] ~20% market share at week 2" of the launch, and that "KV [was] probably on track to achieve expected market share of 47%." The Buckingham Research Group ("Buckingham") issued a similar report on August 21, 2007, "Generic Toprol XL Launch

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[2] KV's fiscal year ends on March 31.

Update," in which it concluded that Generic Metoprolol was critical to KV's share price: "We see continued share gains for generic [Metoprolol] as a key focal point for KV shares."

2. Generic Metoprolol Boosts Earnings The First Two Quarters After Its Launch Ending December 30, 2007

63. After launching Generic Metoprolol on July 26, 2007, KV profited handsomely over the next two quarters with a significant rise in revenues and earnings.

64. On November 20, 2007, KV reported second quarter fiscal 2008 financial results ended September 30, 2007. KV announced "record revenues" of $175.4 million compared to $108.8 million in the same quarter the previous year, reflecting a 61% increase. Generic Metoprolol had contributed $50 million.

65. Wall Street analysts were enthusiastic about the results. Deutsche Bank issued a report on KV that day with the headline, "Outstanding [Second Quarter]; Raising Estimates." The bank "continue[d] to recommend purchase of KV shares based upon the large earnings contribution for the launch of generic Toprol XL, generally solid underlying fundamentals for the company's proprietary brands, as well as KV's underappreciated near term pipeline." Buckingham issued a similar research report that same day, titled, "Preliminary September Quarter Numbers Look Strong; No Change to Positive Thesis."

66. The next quarter sales of Generic Metoprolol continued to drive KV's financial results. On February 15, 2008, KV announced third quarter fiscal 2008 financial results ended December 30, 2008. Revenues in the quarter had increased from approximately $118 million the prior year to $164 million, a 39% increase.

67. Investment analysts again praised the Company's results and focused on the increased revenue from Generic Metoprolol. Deutsche Bank issued a report on February 18, 2008, with the headline, "Robust [Third Quarter] Topline." It then emphasized that, "the

rev[enue] out-performance was driven by solid results across existing Ethex and Ther-Rx business as well as strong continued uptake of generic Toprol XL (100, 200mg)." This analysis was echoed by JP Morgan's research report issued on February 15, 2008, with the title, "Strong In-Line Preliminary 3Q Results." "Sales for the recent quarter came in slightly above our projections, aided by generic Toprol-XL and supported by strong base business trends."

E. IN 2008 GENERIC METOPROLOL WAS NO LONGER ABLE TO CONCEAL THE COMPANY'S FDA AND MANUFACTURING VIOLATIONS AS KV WAS FORCED TO MAKE PARTIAL CORRECTIVE DISCLOSURES

1. In March 2008 FDA Seized KV's Unauthorized Guaifenesin Products Eliminating $39 Million In Annual Sales

68. On March 26, 2008, KV filed its Annual Report on Form 10-K for the fiscal year ended March 31, 2007, with the SEC (the "2007 10-K").[3] The filing disclosed that on March 13, 2008, FDA and the Missouri Department of Health and Senior Services ("MDHSS") had placed a "hold" on KV's inventory of "unapproved products" worth approximately $39 million in annual sales. The products consisted of cough and cold related medicines containing immediate release guaifenesin. The 2007 10-K, however, did not report results for the fourth quarter fiscal 2008 ended March 31, 2008, nor the financial impact of FDA's seizure.

69. KV provided a glimpse of these fourth quarter results by reporting very preliminary fiscal 2008 results on May 30, 2008. This allowed investors and Wall Street analysts to back-out partial results for the fourth quarter ended March 31, 2008. KV "estimate[d] that net revenues for fiscal 2008 [would] increase $158.8 million, or 35.8%, to $602.5 million

[3] KV delayed the filing of the 2007 Form 10-K almost one year, until March 26, 2008, pending the outcome of an investigation by a special committee of the Board of Directors into the Company's stock option grant practices. KV suspended all Form 10-Q and 10-K filings pending the investigation between October 2006 and March 26, 2008. The special committee found that options had been backdated. Claims arising out of backdating option issues are not part of this lawsuit.

due primarily to sales growth of 56.4% experienced in its specialty generics/non-branded products segment." With respect to the fourth quarter, the Company stated that annual "gross profit was adversely impacted by a write-off in the fourth quarter of $5.5 million of inventories of certain unapproved products currently subject to a previous reported FDA hold."

70. These preliminary results were not well-received by Wall Street analysts. Deutsche Bank issued a report on June 1, 2008, called "Prelim[inary Fiscal 2008]; Results Softer than Expected Q4." The key factor in the disappointing fourth quarter results was the lower performance of the generic business due to the FDA hold of KV's cold/cough medicines: "[T]he key Q4 variance relative to our forecast appears to be a softer than expected performance from KV's base generic business, which posted a 16% Y/Y decline, likely related to weakness in cough-cold."

71. Buckingham issued a similar report entitled, "SEC Filing for Extension of F2008 10-K Reveals Earnings Shortfall; Reducing Target." The report added, "Friday's 4% share price decline appears to already reflect disappointment for F2008 results." KV's Class A Shares stock price had dropped from $26.15 on May 29, 2008, to $25.01 per share on May 30. Trading volume exceeded 1.1 million shares, almost six times the prior day's volume.

72. Final fiscal 2008 results, including the fourth quarter, were reported on June 16, 2008 in a press release that was also filed with the SEC on Form 8-K. Revenues for the fourth quarter were $153.0 million compared to $175 million and $164 million in the second and third quarters, respectively. Sales of Generic Metoprolol had fallen to $33.8 million from $50 million in the second quarter for fiscal 2008. "Excluding Metoprolol, sales of other ETHEX products decreased approximately $9.7 million in the fourth quarter compared to the fourth quarter of the prior year."

73. In addition, KV confirmed that fourth quarter results included a write-down of $5.5 million related to the FDA seizure of cough/cold guaifenesin products. The Company also reported that it had abandoned any plans to seek regulatory approvals.

74. Deutsche Bank's analysts found these results disappointing. A report issued on June 16, 2008, and titled, "Aggressive Cost Guidance With No Revenue Parameters," ascribed the weakness in sales to the FDA seizure of KV's cough and cold product and the loss in revenues from that line of products.

> The weakness in the base Q4 Ethex (generic, ex-Toprol XL) performance, which declined 13% Y/Y was in fact due to several factors associated with the company's generic cough-cold business, as we had previously hypothesized. . . . Importantly, the company disclosed that it has decided not to seek regulatory approvals for its extended-release guaifenesin products (FY08 sales of approx. $38M) . . . and therefore had taken a $5.5M inventory write-off on [sic] in Q4.

75. In response to KV's reported fiscal 2008 results, KV's Class A Shares' stock price dropped from $19.91 on Friday, June 13, to $19.05 on Monday, June 16, and $18.49 per share on June 17. Volume exceeded 2.0 million shares and 1.7 million shares, respectively, compared to 0.5 million on June 13.

2. Financial Results For First Quarter Fiscal 2009 (Ending June 30, 2008) Missed Expectations And Disclosed Investigation Into Management Misconduct

76. On August 11, 2008, KV reported results for the first quarter fiscal 2009, ending June 30, 2008, in a press release that was filed with the SEC on Form 8-K. The relevant highlights were the following,

- The Audit Committee of the Board had commenced an independent inquiry into allegations of management misconduct;
- Net revenues for the first quarter fiscal 2009 were $148.9 million, compared with $153 million the prior quarter;

- KV had been unable to meet $10 million worth of orders for generic products, which the Company described as an "unusually large volume of unshipped open orders;" and

- Breaking with prior practice, KV provided earnings projections for fiscal year 2009, ending March 31, 2009: Net revenue between $650 million and $675 million and net income per diluted Class A share between $1.65 and $1.75.

77. First quarter fiscal 2009 results missed Wall Street analyst expectations. Buckingham's August 12, 2008 report was titled, "F1Q09 Misses Consensus/Our Expectations." Net revenues of $148.9 million missed consensus estimates of $162.5 million and Buckingham's estimate of $152.1 million. The miss was due, in part, to lower sales of Generic Metoprolol of only $92.3 million compared to $96.3 million expected by Buckingham.

78. On August 11, 2008, KV also filed Form 10-Q with the SEC for the period ended June 30, 2008. The Form 10-Q included the information set forth in the August 11, 2008 Form 8-K. In addition, it disclosed that the Company had initiated a recall relating to morphine sulfate tablets due to instances of oversized tablets:

> On June 6, 2008, ETHEX initiated a voluntary recall of a single lot of morphine sulfate 60 mg extended-release tablets due to a report that a tablet with as much as double the appropriate thickness was identified and therefore the possibility that other oversized tablets could have been commercially released in the affected lot.
>
> On June 13, 2008, the recall was expanded to include additional specific lots of morphine sulfate 60 mg extended-release tablets and specific lots of morphine sulfate 30 mg extended-release tablets.
>
> On July 8, 2008, a voluntary recall was initiated on specific lots of morphine sulfate 60 mg, 30 mg and 15 mg extended-release tablets in Canada. We accrued a liability of $0.9 million in the fourth quarter of fiscal 2008 for the anticipated cost of the recall.

79. The stock price reacted to the news of August 11 and dropped from $22.36 to $21.42 per share on August 12. Volume of 1.9 million shares was about eight times higher than the prior day's volume.

80. With respect to the Company's earnings guidance for fiscal 2009, Wall Street analysts viewed it as a defensive maneuver to try to minimize the damage to the stock price from the earnings miss. A report issued by Needham & Co. LLC on September 24, 2008, said:

> [W]hile management has for the first time stuck its neck on the line in terms of issuing revenue and EPS guidance for fiscal 2009 . . . the guidance olive branch was largely a defensive measure, to help counter a likely stock price thumping, in our view, following the company's second straight quarter of disappointing bottom line results in 1FQ09 during which should have been two of the most explosive quarters in the company's history.

3. Financial Results For The Second Quarter Fiscal 2009 (Ending September 30, 2008) Substantially Missed Expectations And Disclosed An Expansion Of The Audit Committee's Investigation

81. On November 12, 2008, KV announced second quarter fiscal 2009 results in a filing with the SEC on Form 12b-25. The filing disclosed the expansion of the Audit Committee's investigation into management misconduct:

> [T]he Audit Committee of K-V Pharmaceutical Company, with the assistance of legal counsel, including FDA regulatory counsel, and other advisers, is conducting an internal investigation with respect to a range of specific allegations, from multiple sources, involving, among other items FDA regulatory and other compliance matters and management misconduct. One previously announced FDA recall of a Company product is associated with the investigation as are two new recalls involving several products dated November 7 and November 10, 2008. The Audit Committee presently intends to complete its investigation, deliver its findings and issue its recommended remedial actions before the end of December 2008.

82. The filing also reported dismal financial results. KV reported a net loss of $3.0 million for the second quarter of fiscal 2009 compared to net income of $40.2 million for that

quarter the prior year, or a $0.06 per share loss compared to $0.70 per share gain. Net revenues for the second quarter fiscal 2009 were $144.9 million compared to $148.0 million the prior quarter and $172.9 million for the same quarter the prior year. KV included a chart breaking out the reasons for the loss on an earnings per share basis, showing that Generic Metoprolol and manufacturing problems were responsible for more than 66% of the miss (in bold below):

DESCRIPTION	IMPACT ON DILUTED EPS
Unabsorbed labor and overhead and inventory write-offs related to manufacturing interruptions and inefficiencies in certain generic products	**($0.07)**
Payments to customers related to delayed supply of certain specialty generic products	**($0.02)**
$2.0 million charge related to the settlement of previously disclosed Alabama pricing litigation	($0.02)
Expenses associated with the voluntary recalls of certain generic products	**($0.06)**
Foreign currency mark-to-market transaction loss related to investments denominated in the Indian Rupee	($0.01)
Lower interest income	($0.02)
Increased expenses associated with branded product sales and marketing	($0.10)
Metoprolol 100mg and 200mg price and volume decline	**($0.30)**
Discontinued cough/cold products	**($0.05)**
Lower Ther-Rx net revenues across the product portfolio	($0.08)

Increased research and development spending	($0.05)
All other	$0.02
TOTAL	($0.76)

83. The Company also disclosed the recall of a number of drugs which had caused substantial financial losses. The Company's 12b-25 filing said:

> PRODUCT RECALLS
> ---
>
> As previously announced in the Company's Form 10-Q for the first quarter of fiscal 2009, ETHEX initiated **voluntary recalls of certain lots of morphine sulfate** 30 mg and 60 mg extended-release tablets as a precaution due to the possible presence of oversized tablets, following receipt of two field reports from pharmacists who each identified a single such tablet but did not dispense them. We accrued a liability of $0.9 million in the fourth quarter of fiscal 2008 for the anticipated cost of the recall and increased this accrual by $0.4 million in the second quarter of fiscal 2009.
>
> On October 15, 2008, ETHEX initiated a **voluntary recall to the consumer level of three specific lots of dextroamphetamine sulfate** 5 mg tablets as a precaution due to the possible presence of oversized tablets. We accrued an estimated liability of $0.1 million in the second quarter of fiscal 2009 for the anticipated cost of this recall. On November 7, 2008 ETHEX initiated a **voluntary recall** to the consumer level as a precaution due to the possible presence of oversized tablets of specific lots of **five generic products** in various strengths: propafenone HCL tablets, isosorbide mononitrate extended release tablets, morphine sulfate 15 mg extended release tablets, morphine sulfate immediate release tablets and the 10 mg strength of dextroamphetamine sulfate tablets. The recall involved multiple lots for which we accrued an estimated liability of $2.1 million in the second quarter. On November 10, 2008, ETHEX initiated a voluntary recall to the retail level as a precaution due to the possible presence of oversized tablets. This ETHEX recall affected multiple lots of 18 generic/non-branded products for which we accrued an estimated liability of $2.8 million in the second quarter. No report of any oversized tablets from any of the lots of the products involved in

> these three October/November recalls has been received by ETHEX from any wholesaler, retailer, consumer or caregiver.
>
> As previously announced in the Company's Form 10-Q for the first quarter of fiscal 2009, as a result of the recall in June 2008 of the morphine sulfate extended release tablets, the Company has received multiple adverse event reports from individuals alleging that their adverse events were a result of taking oversized tablets. The Company's subsidiary, ETHEX Corporation, was named as a defendant in a product liability case filed in federal court in June 2008. **During October 2008, three additional lawsuits were filed against ETHEX and/or the Company in various state and federal courts with respect to alleged injuries, including a wrongful death case, pertaining to these morphine sulfate extended release products**, one of which was filed in federal court and is seeking to have a nationwide class certified. The Company cannot provide any assurance that additional lawsuits may not be filed in the future with respect to these products. The Company intends to vigorously defend its interests in these litigations or in the event of future litigation involving these products; however, it cannot give any assurance it will prevail. (Emphasis supplied).

84. As a result of the Company's 12b-25 filing on November 12, 2008, the stock price of Class A Shares suffered a calamitous drop from $14.26 to $5.90 per share on volume exceeding 6.6 million shares.

85. Wall Street analysts again issued unanimously negative reports. Stanford Group Company's ("Stanford") report on November 13, 2008, was titled, "Huge EPS Miss – Significantly Cutting EPS as Brand Business Eroding Faster Than Expected." Stanford further described the results as a "shocking miss," adding that:

> [A]mong the issues were manufacturing inefficiencies and product recalls which resulted in an increase in the company's sales backlog to $18M from $10M at the end of FY1Q09. Also impacting earnings was the decline in generic Toprol volume and price (YoY), declining brand revenue and increased marketing expenses. However, as if the numbers weren't bad enough, the company disclosed that part of the ongoing Audit Committee review includes "FDA regulatory and other compliance matters."

> No further details were provided. This is concerning given the recent product recalls. (Emphasis in original).

86. Buckingham's November 13, 2008 report was also extremely pessimistic, as evidenced from the title, "Form for Delayed 10-Q Highlights Disastrous September Quarter; We Stay Away from Shares." Buckingham further noted that "KV's preliminary revenue forecast disappoints dramatically on branded sales shortfall. . . . We believe that KV's shortfall in earnings and disclosures seriously impair management credibility particularly CEO Marc Hermelin whose family controls the Company through super-voting B shares."

87. The information included in the 12b-25 SEC filing was subsequently repeated in a press release issued on November 17, 2008. The press release was filed with the SEC on Form 8-K on November 21, 2008.

F. KV TERMINATED DEFENDANT HERMELIN FOR CAUSE

88. On December 5, 2008, KV announced in a press release that Defendant Hermelin had been terminated for cause. KV filed the press release with the SEC on Form 8-K.

89. Defendant Hermelin's dismissal was a result of the Audit Committee's investigation into FDA regulatory compliance and management misconduct. Item 5.02 in the Form 8-K, which requires disclosure of the departure of directors and senior executives, stated:

> The Board of Directors of K-V Pharmaceutical Company (the "Company"), acting upon the recommendation of the Audit Committee as a result of its investigation with respect to a range of specific allegations involving, among other things, FDA regulatory and other compliance matters and management misconduct, terminated the employment agreement of Marc S. Hermelin, the Chief Executive Officer of the Company, "for cause" (as that term is defined in such employment agreement).

90. Termination for cause is defined in Defendant Hermelin's employment agreement to require knowledge of all pertinent facts:

> Employer may terminate this Agreement at any time for Cause. For purposes of this Agreement, "Cause" shall mean that (i) Employee has committed a breach of a fiduciary duty, embezzlement, larceny, or has willfully failed to perform his duties to Employer, and in so doing has acted with **full knowledge of all pertinent facts**; and (ii) **such act has had a material and demonstrable adverse effect on Employer**.[4] (Emphasis supplied).

91. The Board of Directors appointed Defendant Van Vliet as interim CEO of the Company and Terry B. Hatfield as non-executive Chairman of the Board. Defendant Hermelin remained a member of the Board.

G. KV SUSPENDED ALL SHIPMENTS OF PRODUCTS BETWEEN DECEMBER 2008 AND JANUARY 2009

1. In December 2008 KV First Suspended All Shipments Of Products Manufactured In Tablet Form

92. On December 23, 2008, KV issued a press release filed with the SEC on Form 8-K that announced that effective December 19, at midnight, the Company had "voluntarily suspended all shipments of all FDA approved drug products in tablet form."

93. The Company was "unable to determine when distribution of tablet-form products [would] resume, or estimate what the financial impact of the recall and suspension [would] be." Nevertheless, KV stated that management believed that the operating results would be "materially adversely affected." The Company had generated net revenues of $159 million in fiscal 2008 from the products subject to the recall, or more than 25% of total net revenues.

94. In addition, following the report of an oversized tablet, KV recalled a single production of Hydromorphone HCl 2mg, a pain management drug. The recall was also disclosed

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[4] *See* Employment Agreement Between the Company and Defendant Hermelin dated December 16, 1997, attached as Exhibit 10(z) to the Form 10-K filed with the SEC on June 30, 1997.

in a separate press release issued on December 23, 2008, and filed in a separate Form 8-K with the SEC.

95. On December 24, 2008, an analyst from Needham & Company opined on the effect of the Company's product recalls on its business:

> Things just seem to be going from bad to worse at KV and management frankly doesn't seem to exactly have a handle on the extent or as importantly the duration of the identified issues the company now faces. **Several recent product recalls culminating with the ouster of long-time Chairman & CEO Mark Hermelin have now turned into suspended shipments on products that generated $160 million in FY08 sales (27% total) and we estimate over $100 million in cash**. Management confirmed that **FDA is now on site conducting inspections** and expert outside regulatory consultants have been hired to help remedy whatever problems the company has uncovered. We still have no clarity on the audit committee investigation that led to Hermelin's ouster though at this point we're starting to think that things can't get much worse. (Emphasis supplied).

96. The December 23, 2008 announcements adversely impacted KV's Class A Shares' stock price. The price per share fell from $5.39 to $2.71 on December 23 on volume of 3.02 million shares. The next day the stock price continued to fall and closed at $1.99 per share on volume of 5.25 million shares.

2. KV Suspended All Shipments In January 2009

97. On January 26, 2009, KV issued a press release filed with the SEC on Form 8-K. KV announced that effective January 22, the Company had "voluntarily suspended the manufacturing and shipment of all its products, other than products it distributes but does not manufacture." KV also announced a nationwide recall of "most" of its products. The Form 8-K further stated that:

> As the Company previously disclosed, the U.S. Food and Drug Administration (the "FDA") began an inspection of the Company in December 2008. These inspectional activities continue and, in addition **representatives of the FDA's Office of Criminal**

> **Investigations ("OCI") have begun participating in discussions with the Company** . . . . the FDA may take enforcement action against the Company, which could include administrative action, civil enforcement by means of judicial proceedings and criminal prosecution of the Company or individuals. (Emphasis supplied).

98. The suspension of all shipments caused KV's Class A Shares' stock price to collapse below one dollar per share. On volume exceeding 8.9 million shares, the stock dropped from $2.47 to $0.51 per share on January 26, 2009. The stock price continued to drop the next day to $0.46 per share on volume exceeding 3.9 million shares.

H. POST CLASS PERIOD EVENTS

1. Defendants Entered Into A Consent Decree With FDA And Admitted That They Knew For Years That KV Was Violating Current Good Manufacturing Practices

99. On March 2, 2009, KV issued a press release and announced that the defendants in the FDA Action (including all Defendants here) had entered into a Consent Decree with FDA (the "Consent Decree") (attached as Exhibit 3). The Consent Decree forced KV to continue the suspension of all manufacturing and distribution activities until the Company could demonstrate compliance with cGMP. To do so, KV would need an independent, third-party-cGMP expert to undertake a review of the Company's facilities and certify compliance. The FDA would subsequently make its own determination whether the facilities were in compliance.

100. The FDA's determination would be largely based on KV fulfilling a series of conditions set forth in paragraph 5 of the Consent Decree (Exhibit 3, Consent Decree). Most relevant to this lawsuit is subsection (J)(1), which states that KV cannot resume operations until, "Defendants report to FDA in writing the actions they have taken to: (1) Correct the cGMP deviations brought to Defendants' attention by FDA since January 1, 2005, the cGMP expert, and any other source including, but not limited to, any experts hired prior to the entry of this Decree."

101. Paragraph 5(J)(1) of the Consent Decree constitutes an admission that Defendants (except Hermelin) here knew that KV was in violation of cGMP since at least January 1, 2005 and failed to take corrective action (Exhibit 3, Consent Decree).

102. As of this date, KV has not been permitted to resume manufacturing operations.

2. Additional Wrongful Death Lawsuits Filed Against KV

103. On November 12, 2008, the Company had announced that it had been sued for wrongful death in connection with the ingestion of a morphine sulfate tablet. At least two more wrongful death lawsuits have been filed since then, with both actions predicated upon ingestion of defective morphine sulfate tablets. One case was filed on March 15, 2009, in Georgia State Court, and the second one in Arizona State Court on April 15, 2009. Additional lawsuits have also been filed alleging personal injuries caused by the same products, although not death.

3. ETHEX Pleaded Guilty to Criminal Charges Relating to FDA Violations

104. On February 25, 2010, KV announced in a press release that it had reached a settlement, subject to court approval, with the U.S. Department of Justice resolving criminal charges against ETHEX. Specifically, KV stated that ETHEX would plead guilty to two felony counts as a result of failing to report the discovery of tablets that did not meet product specifications. ETHEX also agreed to pay over $27 million in aggregate fines, restitution and administrative forfeitures. As a result, KV ceased operations of ETHEX.

(a) Illegal Conduct Set Forth By The Federal Government In The Information

105. On March 2, 2010, the United States Attorney for the Eastern District of Missouri filed a criminal Information (the "Information") in the case of *United States of America v. Ethex Corp.*, No. 4:10-CR-00117-ERW (attached as Exhibit 4). The Information describes the events which led to ETHEX's guilty plea.

106. According to the Information, on May 7, 2008, a California pharmacist reported finding a morphine sulfate tablet that weighed over twice its specified 60 mg dosage strength. (Exhibit 4, Information ¶ 3). The pill had been manufactured by KV with a "BB2" tablet press in its St. Louis Country, Missouri plant and distributed by ETHEX. (*Id*.).

107. The next day, on May 8, 2008, a Canadian distributor relayed another similar report to KV and ETHEX. (*Id*. at ¶ 4). A Canadian pharmacist had found a substantially oversized morphine sulfate tablet, this time in the 30 mg dosage weight. (*Id*.). The Canadian distributor estimated that the oversized tablet weighed 65% more than a regular pill, and contained 60% more morphine sulfate than the 30 mg strength listed on the labeling of the drug. (*Id*.).

108. In light of these reports, KV began an investigation into the "root cause" of the reports of oversized tablets. (*Id*. at ¶¶ 3-5). As part of the investigation, during May and June 2008, KV discovered that the problem was not limited to morphine sulfate tablets but extended to additional products. (*Id*. at ¶¶ 5-6). One of those products was Propanefone – an anti-arrhythmic drug used to treat certain kinds of heart disease. (*Id*. at ¶ 7). According to the Information, KV "concluded that the ingestion of a single higher-than-expected dose of propanefone had the potential to result in a significant increase of the drug in individual patients' blood levels, potentially causing hypotension, convulsions, or an increased risk of assorted heart problems." (*Id*.).

109. Another drug that resulted in oversized tablets was dextroamphetamine sulfate. KV designed and marketed this drug for use primarily by children, typically ages 3-16. (*Id*. at ¶ 8). According to the Information, KV "concluded that ingestion of an oversized tablet of this

drug could create varying results depending on the patient's tolerance and susceptibility to the drug, but adverse effects could include heart problems, hypertension, or tremors." (*Id.*).

110. KV, however, was not able to trace the root cause of oversized tablets to a specific pill press operator or an individual drug. (*Id.* at ¶ 6). KV simply did not know the reason it was producing and distributing oversized and dangerous pharmaceutical drugs. (*Id.* at ¶¶ 6, 9).

111. Unable to determine the cause of the oversized tables, KV issued a limited recall of specific lots of morphine sulfate, 30mg and 60mg strength on June 9 and 13, 2008. (*Id.* at ¶ 5). The recalls were discussed by the Audit Committee and the Board of Directors. (*Id.*). KV did not issue any other recalls at the time, and did not inform the FDA nor the public that it had been unable to identify the root cause of the manufacturing problem and was thus unable to ensure the safety of its products. (*Id.*).

112. On June 18, 2008, KV finally submitted a field alert to the FDA referencing the discovery of oversized morphine sulfate tablets in the 30mg and 60mg strengths. (*Id.*). Critically, KV did not reference the discovery of other oversized tablets. (*Id.*). The field alert submitted to the FDA violated FDA regulations. KV was required pursuant to federal regulations to file a field alert with the FDA within three working days of receiving such information, as set forth in 21 C.F.R. § 314.81(b)(1). (*Id.* at ¶ 16). Because KV had received the information as early as May 7, KV was more than a month late. In the meantime, KV had continued to produce, distribute, and market morphine sulfate tablets.

113. On July 2, 2008, KV employees and management discussed how to respond to the issues regarding the oversized tablets. (*Id.* at ¶ 9). According to the Information, an unidentified KV employee presented options for responding to the discovery of oversized tablets of "various

drugs" on BB2 machines to "Corporate Executive A." (*Id.*). Because subsequently Defendant Hermelin was dismissed for cause, the strongest inference and only reasonable inference is that Defendant Hermelin is "Corporate Executive A." One of the options presented was "to do nothing." (*Id.*). Corporate Executive A was advised that other KV employees did not recommend the "do nothing" option because it did not eliminate risk, was not proactive, and would not enhance KV's reputation with FDA. (*Id.*).

114. Corporate Executive A disregarded the advice of other KV employees, chose to "do nothing," and refused to order any additional recalls or to notify the FDA. (*Id.*). Accordingly, neither the FDA nor the public were informed of KV concerns, of this meeting, or of the danger posed by KV's drugs in the distribution chain.

115. Corporate Executive A also ordered a cover up. During June and July 2008, "Corporate Executive A instructed multiple KV employees to minimize written communications about KV's oversized tablet manufacturing problems, and limit distribution and discussion of any documents discussing these problems given the 'business risk' created by written materials." (*Id.* at ¶ 10). Corporate Executive A purposefully sought to deceive the FDA and the public. He "was worried that communicating problems to FDA could lead to FDA insisting on additional recalls, and also wanted to limit the Audit Committee's investigation." (*Id.*).

116. Corporate Executive A further disregarded the safety of the public for personal benefit. Corporate Executive A "was concerned about the number of complaints that KV had received after two morphine sulfate recalls, and thought it was better to leave the drug products 'on the market.'" (*Id.*).

117. Corporate Executive A was not even deterred by reports of painful consequences for patients. On July 12, 2008, Corporate Executive A was informed that a patient had suffered

"adverse health effects" (not identified in the Information) after ingesting a "crumbly, differently textured, bigger, and thicker than usual 60 mg strength morphine tablet." (*Id*. at ¶ 11). Then, on September 10, 2008, Corporate Executive A was advised of "serious manufacturing issues at KV regarding the manufacturing of morphine sulfate, dextroamphetamine, and propafenone, as well as the failure to report these issues to FDA." (*Id*. at ¶ 12; emphasis supplied).

118. It was not until the Audit Committee instructed Corporate Executive A to begin taking remedial action on September 25, 2008, that KV contacted the FDA. (*Id*. at ¶ 13). A meeting between KV and FDA thus took place on October 10, 2008. (*Id*.). Afterwards, additional product recalls were issued on October 15, 2008; November 7, 2008; November 10, 2008; and December 23, 2008, all discussed *infra*. (*Id*.).

(b) KV's Violations Of FDA Regulations, As Set Forth By the Federal Government In the Information

119. Based on this conduct, the Information enumerated a series of violations under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-394. (Exhibit 4, Information at ¶¶ 14-21). The FDCA regulates the approval, manufacture and distribution of drug products for human consumption.

120. The FDCA requires drug manufacturers to file a new drug application ("NDA") or abbreviated drug application ("ANDA") before manufacturing and marketing most drugs in the United States, pursuant to 21 U.S.C. § 355(a); 21 C.F.R. §§ 314.1-314.90; §§ 314.91-314.99. The NDA and ANDA sets the permissible parameters for a drug's labeling, use, active ingredients, as well as data regarding the chemistry, and manufacturing control methods regarding the drug. 21 U.S.C. § 355(b)(1)(D).

121. Drug manufacturers are further required to prepare and maintain extensive documentary evidence of the manufacturing process. Sections 21 C.F.R. §§ 211.188 and

211.192 require drug manufacturers to prepare drug production and control record, and have a quality control unit review and approve these records before any drugs are distributed. Any unexplained discrepancies or failure to meet specifications must be thoroughly investigated, whether or not the batch was distributed. Any such investigations must extend to other batches of the same drug, or any other drugs that may have been associated with the specific failure or discrepancy. Written records of the investigation are required.

122. Drugs that fail to meet specifications must be documents under 21 C.F.R. §314.81(b)(1)(ii); 21 U.S.C. § 355(k). A field alert must also be filed within three working days if the drug manufacturer has information containing significant chemical changes in distributed drugs or a failure of a distributed drug batch to meet specifications pursuant to 21 C.F.R. §314.81(b)(1).

123. Finally, it is unlawful under 21 U.S.C. § 331(e) to fail to establish or maintain any record or make any report required under 21 U.S.C. § 355(k), including reports required under 21 C.F.R. § 314.80 and § 314.81.

(c) The Information Charged ETHEX With Two Criminal Felony Counts

124. Of all the violations listed in the Information, the United States charged ETHEX with two felony criminal counts in violation of 21 U.S.C. § 331(e), 21 U.S.C. § 333(a)(2), and 18 U.S.C. § 2.

125. Under Count One, on or about September 16, 2008, ETHEX failed to make and submit a field alert report to the FDA regarding ETHEX's discovery of oversized tablets of propafenone 225 mg strength that failed to meet product specifications. (Exhibit 4, Information at ¶¶ 18-19). ETHEX acted "with intent to defraud and mislead." (*Id*. at ¶ 19).

126. Under Count Two, on or about September 16, 2008, ETHEX failed to make and submit a field alert report to the FDA regarding ETHEX's discovery of oversized tablets of dextroamphetamine 5 mg strength that failed to meet product specifications. (*Id*. at ¶¶ 20-21). ETHEX acted "with the intent to defraud and mislead." (*Id*. at ¶ 21).

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

A. The 2004 10-K False And Misleading Statements Concerning Compliance With FDA Regulations Including Current Good Manufacturing Practices

127. On June 14, 2004, after the close of trading, KV filed its Form 10-K for the fiscal year ending March 31, 2004 ("2004 10-K"). In its 2004 10-K, KV explained, in detail, the "extensive" and "complex" governmental regulation of the pharmaceutical manufacturing industry:

> All pharmaceutical manufacturers are subject to extensive regulation by the federal government, principally the FDA, and, to a lesser extent, by state, local and foreign governments. The Federal Food, Drug and Cosmetic Act, or FDCA, and other federal statutes and regulations govern or influence, among other things, the development, testing, manufacture, safety, labeling, storage, recordkeeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Pharmaceutical manufacturers are also subject to certain record keeping and reporting requirements, establishment registration and product listing, and FDA inspections.

128. In particular, KV highlighted the FDA requirement that it "maintain all facilities in compliance with FDA's current Good Manufacturing Practice, or cGMP, requirements." KV also described the severe penalties that KV risked for non-compliance with cGMP:

> Non-compliance with applicable cGMP requirements or the rules and regulations of [governmental] agencies can result in fines, recall or seizure of products, **total or partial suspension of production and/or distribution**, refusal of government agencies to grant pre-market approval or other product applications and criminal prosecution. (Emphasis supplied).

129. In two separate sections of the 2004 10-K, KV asserted that it was in "material compliance" with all "regulatory requirements." In a section entitled "MANUFACTURING AND FACILITIES," KV stated that:

> **We believe that all of our facilities comply with applicable regulatory requirements.** (Emphasis supplied).

And, in a section entitled "RISKS RELATED TO OUR INDUSTRY," KV stated that:

> **We are currently in material compliance with cGMP and are registered with the appropriate agencies.** (Emphasis supplied).

130. At the time KV filed the 2004 10-K, however, the statements that "all [KV] facilities comply with applicable regulatory requirements," and that KV was in "material compliance with cGMP," were materially false and misleading because Defendants knew, and failed to disclose, that (i) in April 2003, FDA issued a Form 483 ("2003 Form 483") to KV that included a "detailed" list of cGMP violations; (ii) in January 2004, FDA issued another Form 483 ("2004 Form 483") to KV identifying cGMP violations that were "the same as, or similar to, prior violations" contained in the 2003 Form 483; and (iii) despite Defendants' assurances to FDA after both the 2003 Form 483 and 2004 Form 483 were issued that the cGMP violations would be rectified, Defendants had not resolved the cGMP violations by the time the 2004 10-K was issued.

B. The 2005 10-K False And Misleading Statements Concerning Compliance With FDA Regulations Including Current Good Manufacturing Practices

131. On June 14, 2005, KV filed its Form 10-K for the fiscal year ending March 31, 2005 ("2005 10-K"). As in its 2004 10-K, KV detailed the "extensive" governmental regulation of the pharmaceutical manufacturing industry and the severe penalties for non-compliance with cGMP. In two separate sections of the 2005 10-K, KV once again asserted that it was in

"material compliance" with all "regulatory requirements." In a section entitled "MANUFACTURING AND FACILITIES," KV stated that:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements.** (Emphasis supplied).

And, in a section entitled "RISKS RELATED TO OUR INDUSTRY," KV stated that:

> **We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.** (Emphasis supplied).

132. At the time the 2005 10-K was filed, however, the statements that "all [KV] facilities comply with applicable regulatory requirements," and that KV was in "material compliance with cGMP," were materially false and misleading because Defendants knew, and failed to disclose, that (i) in January 2005, FDA issued a third Form 483 ("2005 Form 483") to KV identifying cGMP violations that were "the same as, or similar to, prior violations" contained in the 2003 Form 483 and the 2004 Form 483; and (ii) despite Defendants' assurances to FDA that the cGMP violations would be rectified after each of the Forms 483 were issued, Defendants had not resolved the cGMP violations by the time the 2005 10-K was issued.

C. The 2006 10-K False And Misleading Statements Concerning Compliance With FDA Regulations Including Current Good Manufacturing Practices

133. On June 14, 2006, KV filed its Form 10-K for the fiscal year ending March 31, 2006 ("2006 10-K"). As in its two prior 10-Ks, KV detailed the "extensive" governmental regulation of the pharmaceutical manufacturing industry and the severe penalties for non-compliance with cGMP. In two separate sections of the 2006 10-K, KV once again asserted that it was in "material compliance" with all "regulatory requirements." In a section entitled "MANUFACTURING AND FACILITIES," KV stated that:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements.** (Emphasis supplied).

And, in a section entitled "RISKS RELATED TO OUR INDUSTRY," KV stated that:

> **We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.** (Emphasis supplied).

134. At the time the 2006 10-K was filed, however, the statements that "all [KV] facilities comply with applicable regulatory requirements," and that KV was in "material compliance with cGMP," were materially false and misleading because Defendants knew, and failed to disclose, that (i) in March 2006, FDA issued a fourth Form 483 ("2006 Form 483") to KV identifying cGMP violations that were "the same as, or similar to, prior violations" contained in the 2003 Form 483, 2004 Form 483, and 2005 Form 483; and (ii) despite Defendants' assurances to FDA that the cGMP violations would be rectified after each of the Forms 483 were issued, the Defendants had not resolved the cGMP violations by the time the 2006 10-K was issued.

D. False and Misleading Statements In The Second Quarter Fiscal 2008 Financial Results (Ending September 30, 2007) Concerning FDA Violations Relating To The Manufacture of Generic Metoprolol

135. On November 20, 2007, KV issued a press release announcing second quarter fiscal 2008 financial results, and filed the press release with the SEC on Form 8-K on November 21, 2007. KV reported record results based on the launch of Generic Metoprolol. In relevant part, the press release stated:

> Net revenues for the second quarter increased 61% to $175.4 million, compared to $108.8 million for the second quarter of fiscal 2007, with the Company's ETHEX generic/non-branded subsidiary reporting net revenue growth of 102% to $118.4 million.
>
> * * * *
>
> The improvement in net revenues was due to the July 2007 launch of the Company's generic alternative to the 100mg and 200mg strengths of AstraZeneca's Toprol-XL(R), Metoprolol Succinate

> Extended Release Tablets and to continued growth of higher margin branded products in the existing product lines. Net revenue contribution from Metoprolol Succinate Extended Release Tablets during the second quarter of fiscal 2008, which included launch quantities, was $50.4 million.

136. The statements quoted above from the November 20, 2007 press release were materially false and misleading because Defendants knew, and failed to disclose, that, according to the Form 483 issued by FDA on February 2, 2009, KV's manufacturing process for Generic Metoprolol violated FDA regulations, including cGMP, as follows:

- the Generic Metoprolol product line (25mg, 50mg, 100mg, 200mg) had not been developed in a scientifically sound manner with appropriate specifications and process controls. All strengths had historically resulted in drug product of variable quality;
- the Active Pharmaceutical Ingredient used in producing Generic Metoprolol was different than the one used in the design process; and
- the particle size of post-validation lots of Generic Metoprolol was smaller than the one used in an August 5, 2007 validation study.

E. False and Misleading Statements In The Third Quarter Fiscal 2008 Financial Results (Ending December 31, 2007) Concerning FDA Violations Relating To The Manufacture of Generic Metoprolol

137. On February 15, 2008, KV issued a press release announcing third quarter fiscal 2008 financial results, and filed the press release with the SEC on Form 8-K on February 19, 2008. In relevant part, the press release stated:

> Net revenues in [the third quarter for fiscal 2008, ending December 31, 2007] are estimated to be $163.6 million, up 38.7% from fiscal 2007 third quarter net revenues.
>
> * * * *
>
> ETHEX Corporation, KV's generic/non-branded business contributed approximately $102.1 million of revenue, up 57.7% from the prior-year quarter, primarily due to sales of 100mg and 200mg strengths of metoprolol succinate extended release tablets launched in the second quarter of fiscal 2008. ETHEX comprises 62.4% of KV's total revenue for the third quarter period.

138. The statements quoted above from the February 15, 2008 press release were materially false and misleading because Defendants knew, and failed to disclose, that, according to the Form 483 issued by FDA on February 2, 2009, KV's manufacturing process for Generic Metoprolol violated FDA regulations, including cGMP, as follows:

- the Generic Metoprolol product line (25mg, 50mg, 100mg, 200mg) had not been developed in a scientifically sound manner with appropriate specifications and process controls. All strengths had historically resulted in drug product of variable quality;
- the Active Pharmaceutical Ingredient used in producing Generic Metoprolol was different than the one used in the design process; and
- the particle size of post-validation lots of Generic Metoprolol was smaller than the one used in an August 5, 2007 validation study.

F. The 2007 10-K False And Misleading Statements Concerning Compliance With FDA Regulations Including Current Good Manufacturing Practices

139. On March 26, 2008, KV filed its 2007 10-K for the fiscal year ending March 31, 2007. As in its three prior 10-Ks, KV detailed the "extensive" governmental regulation of the pharmaceutical manufacturing industry and the severe penalties for non-compliance with cGMP. In two separate sections of the 2007 10-K, KV once again asserted that it was in "material compliance" with all "regulatory requirements." In a section entitled "MANUFACTURING AND FACILITIES," KV stated that:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements.** (Emphasis supplied).

And, in a section entitled "RISKS RELATED TO OUR INDUSTRY," KV stated that:

> **We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.** (Emphasis supplied).

140. At the time the 2007 10-K was filed, however, the statements that "all [KV] facilities comply with applicable regulatory requirements," and that KV was in "material

compliance with cGMP," were materially false and misleading because Defendants knew, and failed to disclose, that (i) in April 2007, FDA issued a fifth Form 483 ("2007 Form 483") to KV identifying cGMP violations that were "the same as, or similar to, prior violations" contained in the 2003 Form 483, 2004 Form 483, 2005 Form 483, and 2006 Form 483; and (ii) despite Defendants' assurances to FDA that the cGMP violations would be rectified after each of the Forms 483 were issued, the Defendants had not resolved the cGMP violations by the time the 2007 10-K was issued.

G. False and Misleading Statements In The Fiscal 2008 And Fourth Quarter Fiscal 2008 Financial Results (Ending March 31, 2008) Concerning FDA Violations Relating To The Manufacture of Generic Metoprolol

141. On May 30, 2008, KV filed a Form 12b-25 reporting preliminary results for the fourth quarter and fiscal 2008 for the period ending March 31, 2008, which stated:

> [T]he Company estimates that net revenues for fiscal 2008 will increase $158.8 million, or 35.8%, to $602.5 million due primarily to sales growth of 56.4% experienced in its specialty generics/non-branded products segment. The increase in specialty generic net revenues resulted primarily from the launch in July 2007 of the 100mg and 200mg strengths of metoprolol succinate extended-release tablets, which generated estimated net revenues of $119.1 million in fiscal 2008.

142. The statements quoted above from the May 30, 2008 Form 12b-25 were materially false and misleading because Defendants knew, and failed to disclose, that, according to the Form 483 issued by FDA on February 2, 2009, KV's manufacturing process for Generic Metoprolol violated FDA regulations, including cGMP, as follows:

- the Generic Metoprolol product line (25mg, 50mg, 100mg, 200mg) had not been developed in a scientifically sound manner with appropriate specifications and process controls. All strengths had historically resulted in drug product of variable quality;
- the Active Pharmaceutical Ingredient used in producing Generic Metoprolol was different than the one used in the design process; and

- the particle size of post-validation lots of Generic Metoprolol was smaller than the one used in an August 5, 2007 validation study.

H. The 2008 10-K False And Misleading Statements Concerning Compliance With FDA Regulations Including Current Good Manufacturing Practices

143. On June 26, 2008, KV filed its Form 10-K for the fiscal year ending March 31, 2008 ("2008 10-K"). As in its four prior 10-Ks, KV detailed the "extensive" governmental regulation of the pharmaceutical manufacturing industry and the severe penalties for non-compliance with cGMP. In two separate sections of the 2008 10-K, KV once again asserted that it was in "material compliance" with all "regulatory requirements." In a section entitled "MANUFACTURING AND FACILITIES," KV stated that:

> **We believe that all of our facilities are in material compliance with applicable regulatory requirements.** (Emphasis supplied).

And, in a section entitled "RISKS RELATED TO OUR INDUSTRY," KV stated that:

> **We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies.** (Emphasis supplied).

144. At the time the 2008 10-K was filed, however, the statements that "all [KV] facilities comply with applicable regulatory requirements," and that KV was in "material compliance with cGMP," were materially false and misleading because Defendants knew, and failed to disclose, that (i) in March 2008, FDA issued a sixth Form 483 ("2008 Form 483") to KV identifying cGMP violations that were "the same as, or similar to, prior violations" contained in the 2003 Form 483, 2004 Form 483, 2005 Form 483, 2006 Form 483, and 2007 Form 483; and (ii) despite Defendants' assurances to FDA that the cGMP violations would be rectified after each of the Forms 483 were issued, the Defendants had not resolved the cGMP violations by the time the 2008 10-K was issued.

145. The 2008 10-K, in a section entitled "GOVERNMENT REGULATION," further stated that:

> Pharmaceutical manufacturers are also subject to certain record-keeping and reporting requirements, establishment registration and product listing, and FDA inspections.

146. At the time the 2008 10-K was filed, the statement that, "pharmaceutical manufacturers are also subject to certain record-keeping and reporting requirements," was misleading. KV and Corporate Executive A (Hermelin) knew, and failed to disclose that, Corporate Executive A had instructed KV employees not to comply with the reporting requirements with respect to the oversized tablet manufacturing problems. Specifically, the Information states that Corporate Executive A, (i) "instructed multiple KV employees to minimize written communications about KV's oversized tablet manufacturing problems, and limit distribution and discussion of any documents discussing these problems given the 'business risk' created by written material;" (ii) "was worried that communicating problems to FDA could lead to FDA insisting on additional recalls, and also wanted to limit the Audit Committee's investigation;" and (iii) "was concerned about the number of complaints that KV had received after two morphine sulfate recalls, and thought it was better to leave the drug products 'on the market.'"

I. False And Misleading Statements In Form 10-Q For The Quarterly Period Ended June 30, 2008

147. On August 11, 2008, KV filed with the SEC a Form 10-Q for the quarterly period ended June 30, 2008 (the "August 2008 10-Q"). Defendant Hermelin signed the document as Chairman of the Board, Chief Executive Officer, and Principal Executive Office. The August 2008 10-Q stated that,

> The Company was notified during the week of August 4, 2008, that the Audit Committee of its Board of Directors has recently commenced an

> independent inquiry into allegations made by sources not identified to management regarding alleged misconduct by management of the Company . . . . Management is not aware of and does not believe that there has been any misconduct that would have a material impact on the Company's financial results.

148. The statement that "Management is not aware of and does not believe that there has been any misconduct that would have a material impact on the Company's financial results," was false.

(a) Corporate Executive A (Hermelin) knew that the "misconduct by management" referred to Hermelin, or at a minimum, another member of management. As set forth in the Information, Corporate Executive A, (i) "instructed multiple KV employees to minimize written communications about KV's oversized tablet manufacturing problems, and limit distribution and discussion of any documents discussing these problems given the 'business risk' created by written material;" (ii) "was worried that communicating problems to FDA could lead to FDA insisting on additional recalls, and also wanted to limit the Audit Committee's investigation;" and (iii) "was concerned about the number of complaints that KV had received after two morphine sulfate recalls, and thought it was better to leave the drug products 'on the market.'"

(b) Corporate Executive A (Hermelin) also knew that the "misconduct by management" would have a material impact on the Company's financial results because the misconduct concerned overdosed tablets of multiple drugs, additional recalls, and "business risk." Indeed, in late December 2008, when KV announced that it had suspended distribution of all of its tablet-form drugs and would issue recalls for drugs which had already been distributed, the Company acknowledged that its operating results would be "materially adversely affected." The Company had generated net revenues of $159 million – or more than 25% of total net revenues – in fiscal 2008 from the products subject to the recall.

149. Indeed, Defendant Hermelin had been dismissed for cause on December 5, 2008. Defendant Hermelin's dismissal was a result of the Audit Committee's investigation into FDA regulatory compliance and management misconduct. In a press release issued on December 5, KV stated:

> The Board of Directors of K-V Pharmaceutical Company (the "Company"), acting upon the recommendation of the Audit Committee as a result of its investigation with respect to a range of specific allegations involving, among other things, FDA regulatory and other compliance matters and management misconduct, terminated the employment agreement of Marc S. Hermelin, the Chief Executive Officer of the Company, "for cause" (as that term is defined in such employment agreement).

150. Defendant Hermelin also Certified the truthfulness of the August 2008 10-Q as required by the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, as adopted pursuant to § 906. The Certification said: "Based on my knowledge, this [August 2008 10-Q] report does not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

(a) Defendants Hermelin's statement in the Certification was false because he knew that the statement in the August 2008 10-Q that, "Management is not aware of and does not believe that there has been any misconduct that would have a material impact on the Company's financial results," was false.

J. False and Misleading Statements In The First Quarter Fiscal 2009 Financial Results (Ending June 30, 2008) Concerning FDA Violations Relating To The Manufacture of Generic Metoprolol

151. On August 11, 2008, KV reported first quarter fiscal 2009 results in a press release that was filed with the SEC on Form 8-K, stating:

> Net revenues for the first quarter increased 30.2%, or $34.5 million, to $148.9 million, compared with $114.4 million in the

> first quarter of fiscal 2008. . . . . Revenue growth during the quarter was impacted by: . . . . . a net sales gain of 52.6% over the prior year period at the Company's ETHEX generic/non-branded marketing subsidiary, contributed to by sales of 25mg, 50mg, 100mg, and 200mg strengths of metoprolol.

152. The statements quoted above from the August 11, 2008 Form 8-K were materially false and misleading because Defendants knew, and failed to disclose, that, according to the Form 483 issued by FDA on February 2, 2009, KV's manufacturing process for Generic Metoprolol violated FDA regulations, including cGMP, as follows:

- the Generic Metoprolol product line (25mg, 50mg, 100mg, 200mg) had not been developed in a scientifically sound manner with appropriate specifications and process controls. All strengths had historically resulted in drug product of variable quality;
- the Active Pharmaceutical Ingredient used in producing Generic Metoprolol was different than the one used in the design process; and
- the particle size of post-validation lots of Generic Metoprolol was smaller than the one used in an August 5, 2007 validation study.

153. The August 11, 2008 Form 8-K also stated that:

> At the close of the first quarter of fiscal 2009, due to higher-than-expected demand from our customers for certain of our generic products, the Company had an unusually large volume of unshipped open orders for generic products, representing approximately $10 million of net revenues.

154. The statement quoted immediately above from the August 11, 2008 Form 8-K was materially false and misleading because Defendants knew, and failed to disclose, that manufacturing disruptions and inefficiencies, as well as violations of FDA regulations and cGMP, were resulting in a material backlog of unshipped customer orders.

VI. CLASS ACTION ALLEGATIONS

155. Lead Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased KV publicly traded

securities during the Class Period (the "Class"). Excluded from the Class are (i) Defendants; (ii) the officers and directors of the Company; (iii) any subsidiaries and affiliates of the Company; (iv) members of the immediate families of the Individual Defendants and their legal representatives, heirs, successors or assigns; (v) any entity in which Defendants have or had a controlling interest; and (vi) any benefit plan on behalf of employees of the Company and its subsidiaries or affiliates.

156. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. KV had millions of shares of Common Stock outstanding and thousands of shares of Preferreds, owned by thousands of persons.

157. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions that may affect individual Class members include:

- Whether the Exchange Act was violated by Defendants;
- Whether Defendants made false and misleading statements;
- Whether Defendants' conduct constituted a manipulative or deceptive device or contrivance which operated or would operate as a fraud or deceit upon investors;
- Whether Defendants' statements omitted facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- Whether the false and misleading statements and omissions were material;
- Whether Defendants knew or recklessly disregarded that their statements were false and misleading;
- Whether the prices of KV securities were artificially inflated; and
- The extent of damages sustained by Class members and the appropriate measure of damages.

158. Lead Plaintiffs' claims are typical of those of the Class because Lead Plaintiffs and the Class sustained damages arising from Defendants' wrongful conduct.

159. Lead Plaintiffs will adequately protect the interests of the Class and have retained counsel who are experienced in class action securities litigation. Lead Plaintiffs have no interests which conflict with those of the Class.

160. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

VII. ADDITIONAL SCIENTER ALLEGATIONS

161. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading when made. Defendants also knew that such statements or documents would be issued or disseminated to the investing public.

162. Defendants knowingly and substantially participated in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws. As set forth elsewhere herein in detail, Defendants participated in the fraudulent scheme by virtue of (i) Defendants' receipt of information reflecting the true facts concerning the noncompliance of KV's manufacturing practices with FDA regulations, including cGMP; (ii) Defendants' control over, and/or receipt and/or modification of KV's materially false and misleading misstatements and omissions; and (iii) Defendants' positions with the Company which made them privy to confidential proprietary information concerning the true manufacturing practices and conditions at KV.

163. In particular, as set forth above, and as alleged by the FDA Action, Defendants knew of the FDA violations, the continuous nature of the violations, the Forms 483, and had discussions with the FDA concerning those violations:

> The deficiencies observed by the FDA at the most recent inspection in February 2009 are the same as, or similar to, prior violations observed by FDA at several other inspections conducted during the last eight years.
>
> Defendant's noncompliance has continued despite repeated warnings from FDA regarding its cGMP violations. At the conclusion of each FDA inspection in 4/2003, 1/2004, 1/2005, 3/2006, 4/2007, 3/2008, 8/2008 and 2/2009, FDA investigators prepared and issued a detailed List of Inspectional Observations, Form FDA-483, to Defendants, notifying them of the investigators' observations. **The FDA investigators discussed the violations listed in the Form FDA-483s with Defendants**, who expressed a desire to correct the deficiencies. Nevertheless, FDA investigators have continued to observe cGMP violations at subsequent inspections. (Exhibit 1, FDA Cmpt. at ¶¶ 23-24) (emphasis supplied).

164. The Information filed by the United States with this District Court further provides additional evidence in support of a strong inference of scienter. According to the Information, ETHEX committed at least two criminal felony violations "with the intent to defraud and mislead." In addition, the Information states additional facts that raise a strong inference of scienter, including the following:

> Corporate Executive A, (i) "instructed multiple KV employees to minimize written communications about KV's oversized tablet manufacturing problems, and limit distribution and discussion of any documents discussing these problems given the 'business risk' created by written material;" (ii) "was worried that communicating problems to FDA could lead to FDA insisting on additional recalls, and also wanted to limit the Audit Committee's investigation;" and (iii) "was concerned about the number of complaints that KV had received after two morphine sulfate recalls, and thought it was better to leave the drug products 'on the market.'"

165. Moreover, the strong inference suggests that Corporate Executive A, whom the Information states is a former executive who was "an agent of ETHEX" and "also a corporate executive at KV," is Hermelin. As seen in the Information, Corporate Executive A (Hermelin) engineered and participated in the cover-up. Moreover, as he was CEO of KV, his scienter is imputable to the Company.

166. Scienter is also supported by the Consent Decree executed by Defendants (Exhibit 3). In section 5(J)(1), Defendants (except Hermelin) admit that they knew of the FDA violations since January 1, 2005. That section states that KV will not be able to resume operations until, "Defendants report to FDA in writing the actions they have taken to: (1) Correct the cGMP deviations brought to Defendants' attention by FDA since January 1, 2005, the cGMP expert, and any other source including, but not limited to, any experts hired prior to the entry of this Decree."

167. Defendant Hermelin's scienter is also evidenced by his involuntary termination for cause as CEO by the Board of Directors on December 5, 2008. His employment agreement defines "cause" to be limited to instances in which Defendant Hermelin has "full knowledge." The employment agreement states:

> Employer may terminate this Agreement at any time for Cause. For purposes of this Agreement, "Cause" shall mean that (i) Employee has committed a breach of a fiduciary duty, embezzlement, larceny, or has willfully failed to perform his duties to Employer, and in so doing has acted with **full knowledge of all pertinent facts**; and (ii) such act has had a material and demonstrable adverse effect on Employer.

168. Because Defendants Hermelin and Van Vliet were CEOs of the Company at all times during the Class Period, their scienter is ascribed to the Company. Similarly, because

Defendant Bleser was an executive officer of the Company, her scienter is also attributable to KV.

169. Defendants knew about the materially false and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraudulent scheme described in this Complaint could not have been perpetrated over a substantial period of time, as has occurred here, without the knowledge, participation, and complicity of the executives at the highest level of the Company, including the Individual Defendants.

VIII. EXPERT ANALYSIS

A. OPINION OF FDA COMPLIANCE EXPERT REGARDING SIGNIFICANCE OF OBSERVABLE CONDITIONS IN FORMS 483

170. Lead Plaintiffs attach the expert report of Benjamin L. England, Esq. as Exhibit 5 (the "England Affidavit"). Mr. England is a compliance consultant with seventeen years of experience as a FDA official, including four years as an investigator and compliance officer at FDA, six years as a special agent with FDA's Office of Criminal Investigations and three years as a regulatory counsel for FDA's Associate Commissioner for Regulatory Affairs. In private practice Mr. England assists clients in FDA compliance and enforcement matters, including responding to Form 483s. A copy of his *curriculum vitae* is attached to his report.

171. Based on his experience and his review of the relevant documents, Mr. England opined that conduct that falls outside FDA's GMP requirements violates the FDCA and amounts to a violation of federal law. (Exhibit 5, England Aff., at ¶ 7). Mr. England additionally opined that observations made by FDA investigators during a drug inspection equate with observable and documented evidence of a violation of federal law. (*Id*. at ¶ 5). Forms 483, such as the one issued to KV in 2009, document conditions and practices that are notably deficient with respect to drugs, thereby resulting in an adulteration violation of FDA GMP requirements. (*Id*. at ¶ 4).

172. Accordingly, the England Affidavit establishes what is indicated by the FDA Complaint: that the observations and deficiencies reported on the Form 483 were violations of GMP. This is consistent with the FDA Complaint's alternation between the terms "deficiencies," "observed" and "violations," and establishes that the FDA was using these terms interchangeably in reference to KV. (Exhibit 1, FDA Cmpt. at ¶¶ 23-24) ("The deficiencies observed by the FDA at the most recent inspection in February 2009, are the same as, or similar to, prior **violations observed** by FDA …. The FDA investigators discussed **the violations** listed in the Form FDA-483s with Defendants, who expressed a desire to correct **the deficiencies**.")

B. OPINION OF CHARTERED FINANCIAL ANALYST REGARDING AVAILABILITY OF INFORMATION TO PUBLIC REGARDING KV'S RECEIPT OF FORM 483s

173. Lead Plaintiffs attach the expert report of Candace L. Preston as Exhibit 6 (the "Preston Affidavit"). Ms. Preston is a degreed Chartered Financial Analyst with extensive experience analyzing publicly traded securities. She has provided expert testimony in other class actions brought pursuant to the United States securities laws.

174. Upon reviewing the relevant documents and data, Ms. Preston opined that investors and the market did not learn of the existence of the Forms 483 issued to Colonial by FDA in the years 2003 – 2009 until March 2, 2009, when FDA filed its Complaint against the Company. (Exhibit 6, Preston Aff., at ¶ 6).

175. In reaching this opinion, Ms. Preston examined channels through which information generally becomes available to the market, including *Dow Jones/Factiva* and *Bloomberg Professional Service*.[5] *Id*. at ¶ 9. Ms. Preston found that there was no mention of

[5] *Dow Jones/Factiva* and *Bloomberg Professional Service* are databases that carry information aggregated from numerous media outlets, including *The Wall Street Journal*, *The*

(continued . . .)

KV's receipt of Forms 483 during the period April 1, 2003 through February 24, 2009 in these databases. *Id*.

176. Ms. Preston also reviewed analyst reports regarding KV in the *Thomson/Reuters* database. *Id*. at ¶ 10. Again, KV's receipt of Forms 483 during the Class Period was never mentioned. *Id*.

177. Ms. Preston also reviewed KV's filings with the SEC during the period January 1, 2003 to March 10, 2010. *Id*. at ¶ 14. The only references to KV's receipt of Forms 483 appeared in 8-Ks filed after the Class Period, on February 26, 2009, April 30, 2009 and July 24, 2009. *Id*.

178. Accordingly, Ms. Preston conducted a thorough review of the materials and information that were available to the market during the Class Period, and concluded that, during the Class Period, the market did not learn of KV's receipt of FDA Forms 483 as a result of inspections between April 2003 and February 2009. Moreover, Ms. Preston concluded that it was not until March 2, 2009, when the FDA filed its Complaint, that the market learned of these Forms 483. Based on the Preston Affidavit, it is therefore apparent that the information that KV had received Forms 483 describing numerous, continuing violations of cGMP during the Class Period was not disseminated or readily accessible to the market and incorporated into the Company's stock price until March 2, 2009.

IX. LOSS CAUSATION/ECONOMIC LOSS

179. During the Class Period, as detailed herein, Defendants engaged in a course of conduct that artificially inflated the price of KV securities and operated as a fraud or deceit on the Class Period purchases of KV securities by making materially false and misleading

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(. . . continued)
New York Times, international, local and regional newspapers, as well as newswires, magazines and industry publications.

statements and failing to disclose that KV (i) had been systematically violating FDA regulations, including cGMP, ignoring the corrective requirements of the several Forms 483 issued to it throughout the Class Period, and (ii) manufactured and sold Generic Metoprolol in violation of FDA regulations. Defendants also made materially false and misleading statements that operated as a fraud or deceit when they failed to disclose that KV had manufactured and distributed, and continued to manufacture and distribute, defective pharmaceutical drugs that were dangerous to the public. Later, however, when Defendants' prior materially false and misleading statements and fraudulent conduct began to be disclosed and became known to the market, the price of KV securities declined precipitously as the prior artificial inflation was removed from the price of KV securities. As a result of their purchases of KV securities at artificially inflated prices during the Class Period, Lead Plaintiffs and other members of the Class suffered a substantial economic loss (i.e., damages under the federal securities laws) as the truth was revealed.

180. For purposes of alleging loss causation, the price decline in KV's securities, as detailed herein, was a direct result of the nature and extent of materially false and misleading statements and omissions revealed to investors and the market, as follows:

181. **On May 30, 2008**, KV reported preliminary fiscal 2008 results and certain information concerning fourth quarter fiscal 2008. KV "estimate[d] that net revenues for fiscal 2008 [would] increase $158.8 million, or 35.8%, to $602.5 million due primarily to sales growth of 56.4% experienced in its specialty generics/non-branded products segment." With respect to the fourth quarter, the Company stated that annual "gross profit was adversely impacted by a write-off in the fourth quarter of $5.5 million of inventories of certain unapproved products currently subject to a previous reported FDA hold."

(a) These preliminary results were not well-received by Wall Street analysts. Deutsche Bank issued a report on June 1, 2008, called "Prelim[inary Fiscal 2008]; Results Softer than Expected Q4." The key factor in the disappointing fourth quarter results was the lower performance of the generic business due to the FDA hold of KV's cold/cough medicines: "[T]he key Q4 variance relative to our forecast appears to be a softer than expected performance from KV's base generic business, which posted a 16% Y/Y decline, likely related to weakness in cough-cold."

(b) Buckingham issued a similar report on June 2, 2008, entitled, "SEC Filing for Extension of F2008 10-K Reveals Earnings Shortfall; Reducing Target." The report added, "Friday's 4% share price decline appears to already reflect disappointment for F2008 results."

(c) KV's Class A Shares' stock price dropped from $26.15 on May 29, 2008, to $25.01 per share on May 30. Volume exceeded 1.1 million shares, almost six times the prior day's volume.

(d) KV's Class B Shares' stock price dropped from $26.13 on May 29, 2008, to $25.07 per share on May 30. Volume reached 5,800 shares, more than 11 times the prior day's volume.

(e) The price of KV's Preferreds fell from $118.125 on May 29, 2008, to $113.375 per share on May 30.[6]

182. **On June 16, 2008**, KV reported final fiscal 2008 results including fourth quarter results. Revenues in the fourth quarter were $153.0 million compared to $175 million and $164 million in the second and third quarters, respectively. Sales of Generic Metoprolol had fallen to

[6] Price information for the Preferreds was obtained from FactSet Research Systems, Inc., a leading provider of financial data and analytic applications for investment management and investment banking firms.

$33.8 million from $50 million in the second quarter for fiscal 2008. Importantly, "excluding Metoprolol, sales of other ETHEX products decreased approximately $9.7 million in the fourth quarter compared to the fourth quarter of the prior year." In addition, KV confirmed that fourth quarter results included a write-down of $5.5 million related to the FDA seizure of KV's cough/cold guaifenesin products. The Company also reported that it had abandoned any plans to seek regulatory approvals for those products.

(a) Deutsche Bank's issued a report stating:

> The weakness in the base Q4 Ethex (generic, ex-Toprol XL) performance, which declined 13% Y/Y was in fact due to several factors associated with the company's generic cough-cold business, as we had previously hypothesized. . . . Importantly, the company disclosed that it has decided not to seek regulatory approvals for its extended-release guaifenesin products (FY08 sales of approx. $38M) . . . and therefore had taken a $5.5M inventory write-off on [sic] in Q4.

(b) KV's Class A Shares' stock price dropped from $19.91 on Friday, June 13, to $19.05 on Monday, June 16, and $18.49 per share on June 17. Volume exceeded 2.0 million shares and 1.7 million shares, respectively, compared to 0.5 million on June 13.

(c) KV's Class B Shares' stock price dropped from $19.83 on Friday, June 13, to $19.05 on Monday, June 16, and $18.34 per share on June 17. Volume reached 5,100 shares and 776 shares on June 16 and 17, respectively, compared to 300 shares on June 13.

(d) The price of KV's Preferreds fell from $102.125 on Friday, June 13, to $96.375 on Monday, June 16, and $94.750 per share June 17.

183. **On August 11, 2008**, after the market closed, KV issued a press release reporting results for the first quarter for fiscal 2009 ended June 30, 2008.

(a) In the press release, the Company revealed that the Audit Committee of its Board of Directors had begun an independent inquiry into allegations of management misconduct. Less

than an hour after KV issued the press release, Bloomberg issued a news report with the headline, "KV Pharmaceutical Says It Starts Probe of Misconduct." The Bloomberg story added that "KPMG LLP, KV Pharmaceutical's accountant, told the company it will be unable to complete its interim financial information for the first quarter of fiscal 2009 until the audit committee finishes the inquiry."

(b) The St. Louis Post Dispatch reported on August 13, that "KV Pharmaceutical Co. reported a strong first quarter, but an audit of the financial results was stalled by complaints of alleged management misconduct."

(c) The stock price for Class A Shares fell from $22.36 on August 11, to $21.42 per share on August 12, on volume exceeding 1.9 million shares, almost nine times the prior day's volume.

(d) The stock price for Class B Shares fell from $22.34 on August 11, to $21.35 per share on August 12, on volume of 3,000 shares, almost 1.5 times the prior day's volume.

(e) The price of KV's Preferreds fell from $104.375 on August 11, to $101.125 per share on August 12.

184. **On November 13, 2008**, prior to the market's open, KV issued a press release announcing it had filed Form 12b-25 with the SEC, which delayed the filing of KV's Form 10-Q for the second quarter fiscal 2009 for the period ended September 30, 2008, and reported results for the same period.

(a) Form 12b-25 revealed new details about the Audit Committee's investigation into alleged management misconduct that had been previously disclosed on August 11, 2008. KV revealed that the investigation now involved (i) "the assistance of legal counsel, including FDA

regulatory counsel, and other advisers," and (ii) "specific allegations, from multiple sources" about "FDA regulatory and other compliance matters and management misconduct."

(b) The Form 12b-25 also reported financial results for the second quarter for fiscal 2009. The Company incurred a $0.06 loss per share on net revenues of $144 million, compared to Wall Street analyst expectations of $0.38 earnings per share on net revenues of $161 million. The loss was a result, in large part, of "manufacturing interruptions and inefficiencies" and "expenses associated with the voluntary recalls of certain generic products."

(c) The new revelations about the investigation and the financial results were described by Wall Street analysts as reflecting a "disastrous September quarter"[7] and a "shocking miss."[8] One analyst further wrote, "as if numbers weren't bad enough, the company disclosed that part of the ongoing Audit Committee review includes 'FDA regulatory and other matters.' No further details were provided. This is concerning given the recent product recalls."[9]

(d) The stock price per share for Class A Shares fell from $14.26 on November 12, to $5.90 on November 13, a 58% drop. Volume exceeded 6.6 million shares, almost 30 times the prior day's volume.

(e) The stock price per share for Class B Shares fell from $14.26 on November 12, to $5.875 on November 13, on volume exceeding 50,000 shares, almost 25 times the prior day's volume.

(f) The price of KV's Preferred Stock fell from $74.50 on November 12, to $44.25 per share on November 13.

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[7] Buckingham Research Group report on KV, dated November 13, 2008, and titled, "Form For Delayed 10-Q Highlights Disastrous September Quarter; We Stay Away From Shares."

[8] Stanford Group Company report on KV, dated November 13, 2008, and titled, "KVA: Huge EPS Miss – Significantly Cutting EPS as Brand Business Eroding Faster Than Expected."

[9] *Id.* (Emphasis in original).

185. **On December 23, 2008**, during market trading hours, KV issued a press release announcing (i) the suspension of all shipments of its approved tablet-form drugs, and (ii) a nationwide, single-lot recall of Hydromorphone HCl (2mg) due to the discovery of an oversized tablet. The Company admitted that the "operating results [would] likely [] be materially adversely affected." The products suspended had generated revenues of $159 million in fiscal 2008 out of total revenues of $601 million for the Company.

(a) The stock price per share for Class A Shares fell from $5.39 on December 22, to $2.71 on December 23. Volume exceeded 3.0 million shares, which was ten times the prior day's volume. The stock price per share for Class B Shares fell from $5.35 on December 22, to $2.82 on December 23, on volume of 12,600 shares, over five times the prior day's volume. Bloomberg published a news article on December 23, with the headline, "KV Pharmaceutical Dives After Halting Drug Shipments." The Bloomberg article added that KV "lost half its value in New York trading after the drugmaker, announcing a third recall of medicines that may contain excess doses, stopped shipping prescription tablets."

(b) On December 24, the stock price per share for Class A Shares fell to $1.99, from $2.71 on December 23. Volume for Class A Shares reached 5.25 million shares, almost 17 times the volume on the day prior to the disclosure. On December 24 the stock price per share for Class B Shares fell to $2.18, from $2.82 on December 23. Volume for Class B Shares reached 13,200 shares, over 5 times the volume on the day prior to the disclosure. Bloomberg published a news article on December 24, titled, "KV's Pharmaceutical's Oversize Pain Pill Sinks Shares Second Day." The Bloomberg article further said, "KV Pharmaceutical Co., lost almost two-thirds of its value in the last two days after saying it halted shipping prescription tablets and began its third recall linked to oversized pills."

(c) The price of KV's Preferred Stock fell from $41.125 on December 22, to $33.125 on December 23, and $27.00 per share on December 24.

186. **On January 26, 2009**, prior to the market open, KV issued a press release announcing the it had "suspended the manufacturing and shipping of all its products, other than products it distributed but does not manufacture." The suspension had begun on January 22, 2009. Additionally, the Company would recall most of its products. Once again, the Company admitted that the suspension of all manufacturing would have a "material adverse effect" on its financial condition. KV also disclosed that FDA's Office of Criminal Investigations had begun participating in the investigations.

(a) The stock price per share for Class A Shares fell from $2.13 on January 23 (Friday), to $0.51 on January 26 (Monday). Volume exceeded 8.9 million shares, which was ten times the volume on January 23.

(b) The stock price per share for Class B Shares fell from $2.25 on January 23 (Friday), to $0.58 on January 26 (Monday). Volume exceeded 32,000 shares, which was six times the volume on January 23.

(c) The price of KV's Preferred Stock fell from $34.875 on January 23 (Friday), to $23.50 per share on January 26 (Monday).

187. Each of the declines in the Company's securities prices were significant after taking into account changes on the same days in the overall securities market and in relevant industry indices. Furthermore, as set forth above, each of the securities price declines is attributable to the disclosure of previously concealed information relating to the materially false or incomplete statements alleged herein. The timing and magnitude of KV's securities price declines negate any inference that the losses suffered by Lead Plaintiffs and other Class members

were caused by other changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct.

188. In sum, as the truth about Defendant's fraud was revealed, the Company's securities prices declined, the artificial inflation came out of the price of the securities, and Lead Plaintiffs and other members of the Class suffered damages.

X. NO SAFE HARBOR

189. KV's "Safe Harbor" warnings accompanying its forward-looking statements issued during the Class Period were ineffective to shield those statements from liability.

190. Defendants are also liable for any false forward-looking statements pleaded because, at the time each forward-looking statement was made, the speaker knew that the forward-looking statement was false and the forward-looking statement was authorized and/or approved by an executive officer of KV who knew that the forward-looking statement was false. None of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

XI. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

191. Lead Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's securities traded in efficient markets;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(e) Lead Plaintiffs and other members of the Class purchased KV securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

192. At all relevant times, the markets for KV securities were efficient for the following reasons, among others:

(a) KV's Common Stock actively traded in the New York Stock Exchange;

(b) As a regulated issuer, KV filed periodic public reports with the SEC;

(c) Numerous financial analysts from Wall Street regularly followed the Company and issued periodic research reports; and

(d) KV regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

COUNT I

For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against Defendants KV and Hermelin

193. Lead Plaintiffs repeat and reallege each and every allegation above as if set forth fully herein. This claim is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, on behalf of Lead Plaintiffs and all other members of the Class, against Defendants KV and Hermelin.

194. Throughout the Class Period, Defendants KV and Hermelin individually, and in concert, directly or indirectly, by the use and means of instrumentalities of interstate commerce, the mails and facilities of national securities exchange, employed devices, schemes and artifices to defraud, made untrue statements of material fact and/or omitted to state material facts necessary to make statements made not misleading, and engaged in acts, practices and a course of business which operated as a fraud and deceit upon Class members, in violation of Section 10(b) of the Exchange Act and Rule 10(b)-5(b) promulgated thereunder. Defendants KV's and Hermelin's false and misleading statements and omissions were made with scienter and were intended and did, as alleged herein, (i) deceive the investing public, including Lead Plaintiffs and the other members of the Class; (ii) artificially create, inflate and maintained the market for and market price of the Company's securities; and (iii) cause Lead Plaintiffs and the other members of the Class to purchase KV securities at inflated prices.

195. Defendants KV and Hermelin initiated or pursued a scheme and course of conduct which concealed (i) that the Company was in consistent violation of FDA regulations and cGMP, and (ii) the Forms 483 issued to the Company by FDA, in an effort to maintain an artificially high price for the Company's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Defendants KV and Hermelin are sued as primary participants in the wrongful and illegal course of conduct charged herein.

196. By concealing the Company's violations of FDA regulations and cGMP, failing to disclose the Forms 483, and making other false statements alleged herein, Defendants KV and Hermelin presented a misleading picture of KV's business and prospects. This caused and maintained artificial inflation in the trading prices of the Company's securities throughout the Class Period and until the truth came out.

197. Defendants KV and Hermelin were individually and collectively responsible for making the statements and omissions alleged herein, by virtue of having prepared, approved, signed and/or disseminated documents which contained untrue statements of material fact and/or omitted facts necessary to make the statements therein not misleading and/or making direct statements to the investing public.

198. During the Class Period, Defendant Hermelin occupied the highest executive position at KV, owned a majority of the voting stock of the Company, and was privy to non-public information concerning the Company. He knew the adverse facts specified herein and omitted to disclose those facts.

199. As set forth herein, Defendants KV and Hermelin made the false statements and omissions knowingly or intentionally, or in such an extremely reckless manner as to constitute willful deceit and fraud upon Lead Plaintiffs and other members of the Class who purchased KV securities during the Class Period. Throughout the Class Period, Defendants KV and Hermelin had a duty to disclose new information that came to their attention which rendered their prior statements to the market false and misleading.

200. Defendants KV's and Hermelin's false and misleading statements and omissions were made in connection with the purchase or sale of the Company's securities.

201. In ignorance of the false and misleading nature of Defendants KV's and Hermelin's statements and/or in reliance upon the integrity of the market price of KV securities, Lead Plaintiffs and the other members of the Class purchased or otherwise acquired KV securities at artificially inflated prices during the Class Period. But for the fraud, Lead Plaintiffs and the other Class members would not have purchased or acquired KV securities at artificially inflated prices.

202. The market price for KV's securities declined materially upon the public disclosure of the facts that had been previously misrepresented and/or omitted by Defendants KV and Hermelin, as described above.

203. Lead Plaintiffs and the other members of the Class were substantially damaged as a direct and proximate result of their purchase of KV securities at artificially inflated prices and the subsequent decline in the price of the securities when the truth was disclosed.

204. Defendants KV and Hermelin acted with scienter throughout the Class Period, in that they had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein. Defendant Hermelin was CEO of the Company, a member of the Board, and Chairman through a substantial portion of the Class Period, and was therefore directly responsible for the false and misleading statements and/or omissions disseminated to the public through press releases, statements to the news media, and filings with the SEC.

205. In committing the wrongful acts alleged herein, Defendants KV and Hermelin have pursued or joined in the pursuit of a common course of conduct and acted in concert with one another in furtherance of their common plan. This course of conduct or scheme was designed to and did: (i) conceal that KV was in violation of FDA regulations, including cGMP, and the Forms 483 issued by FDA before and during the Class Period; (ii) maintain Hermelin's executive and directorial positions at KV and the profits, power and prestige that Hermelin enjoyed as a result of those positions; and (iii) deceive the investing public, including the securities holders of KV, regarding the Company's business and prospects.

206. Defendants KV and Hermelin accomplished their common enterprise and/or common course of conduct by causing the Company to purposefully violate FDA regulations, including cGMP, conceal the Forms 483, and make false and misleading statements about KV's

compliance with FDA and cGMP regulations and requirements. Each of these Defendants was a direct, necessary and substantial participant in the common enterprise and/or course of conduct complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, Defendants KV and Hermelin each acted with knowledge of the primary wrongdoing and was aware of its or his overall contribution to and in furtherance of the wrongdoing.

207. This claim was brought within two years after discovery of this fraud and within five years of the making of the statements and fraudulent conduct alleged herein to be materially false and misleading.

208. By virtue of the foregoing, Defendants KV and Hermelin have violated Section 10(b) of the Exchange Act and Rule 10(b)-5 promulgated thereunder, and are liable to Lead Plaintiffs and the other members of the Class, each of whom has been damaged as a result of such violation.

COUNT II

For Violation of §10(b) of the Exchange Act and Rule 10b-5(a) and (c) Promulgated Thereunder Against Defendants Van Vliet and Bleser

209. Lead Plaintiffs repeat and reallege each and every allegation above as if set forth fully herein. This claim is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder, on behalf of Lead Plaintiffs and all other members of the Class against Defendants Van Vliet and Bleser.

210. During the Class Period, Defendants Van Vliet and Bleser carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did (a) deceive the investing public, including Lead Plaintiffs and other members of the Class, as alleged

herein, and (b) caused Lead Plaintiffs and other members of the Class to purchase KV securities at artificially inflated prices.

211. Defendants Van Vliet and Bleser employed devices, schemes, and artifices to defraud and engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of KV securities in an effort to maintain artificially high market prices in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Lead Plaintiffs sue Defendants Van Vliet and Bleser as primary participants in the wrongful and illegal conduct charged herein.

212. Defendants Van Vliet and Bleser directly and indirectly, by the use and means of instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of KV as specified herein.

213. Defendants Van Vliet and Bleser engaged in transactions, practices and a course of conduct that operated as a fraud and deceit upon the purchasers of KV securities. Defendants Van Vliet and Bleser employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information, and engaged in acts, practices, and a course of conduct in an effort to assure investors of KV's value and performance and continued substantial growth.

214. Defendants Van Vliet and Bleser acted with the requisite scienter in that they had actual knowledge of the misrepresentations and omissions of material fact as set forth herein. Such material misrepresentations and/or omissions were made knowingly and for the purpose and effect of concealing the violations of FDA regulations, including cGMP, and the Forms 483.

215. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of KV securities was

artificially inflated during the Class Period. In ignorance of the fact that the market price of KV securities was artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, and/or upon the integrity of the market, and/or the absence of material adverse information that was known by Defendants Van Vliet and Bleser but not disclosed in public statements by Defendants during the Class Period, Lead Plaintiffs and the other members of the Class acquired KV securities during the Class Period at artificially high prices and were damaged thereby.

216. At the time of said misrepresentations and omissions, Lead Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Lead Plaintiffs and the members of the Class known the truth regarding the material undisclosed facts alleged herein, which was not disclosed by Defendants, Lead Plaintiffs and other members of the Class would not have purchased or otherwise acquired KV securities at artificially inflated prices. By virtue of the foregoing, Defendants Van Vliet and Bleser have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

217. As a direct and proximate result of Defendants Van Vliet's and Bleser's wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their purchases of KV securities.

218. This claim was brought within two years after discovery of this fraud and within five years of the making of the statements alleged herein to be materially false and misleading and of the occurrence of the conduct alleged herein to violate Section 10(b) and Rule 10b-5.

COUNT III

For Violation of §20(a) of the Exchange Act Against All Individual Defendants

219. Lead Plaintiffs repeat and reallege each and every allegation above as if set forth fully herein. This claim is brought pursuant to Section 20(a) of the Exchange Act on behalf of Lead Plaintiffs and all other members of the Class against Defendants Hermelin, Van Vliet, and Bleser.

220. As alleged herein, KV is liable to Lead Plaintiffs and the other members of the Class who purchased or acquired KV securities based on materially false and misleading statements and omissions set forth above, pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

221. Throughout the Class Period, Defendants Hermelin, Van Vliet, and Bleser were controlling persons of KV within the meaning of §20(a) of the Exchange Act, and culpable participants in the fraud, as detailed herein.

222. Defendant Hermelin exercised control of KV from the beginning of the Class Period through December 5, 2008, for the following reasons:

(a) Defendant Hermelin had a substantial ownership of super voting Class B shares throughout the Class Period. In fiscal 2008, Defendant Hermelin owned 66% of the Class B Shares and 10.5% of the Class A Shares, thus having majority control of all voting shares of the Company;

(b) The FDA Complaint seeking to enjoin and restrain the Company from manufacturing and distributing pharmaceutical products named Defendant Hermelin as a defendant precisely because Defendant Hermelin had control of the Company and the power to have the Company manufacture and distribute pharmaceutical products;

(c) Defendant Hermelin was CEO from the beginning of the Class Period through December 5, 2008, a Director throughout the Class Period, and Chairman of the Board of Directors from August 2006 through December 5, 2008;

(d) Defendant Hermelin had direct involvement in the day-to-day operations of the Company, including discussions and meetings with FDA;

(e) Defendant Hermelin was ultimately responsible for ensuring that the Company's public disclosures were not false and misleading. Consistent with that responsibility, he signed each of KV's Forms 10-K during the Class Period. In addition, pursuant to Sections 302 and 906 of the Sarbanes-Oxley Act, Defendant Hermelin also certified the accuracy of the Company's Forms 10-Ks issued during the Class Period and the effectiveness of the Company's disclosures.

223. Defendant Van Vliet exercised control of KV from September 2006 through the end of the Class Period for the following reasons:

(a) Defendant Van Vliet was (i) Chief Administration Officer from September 2006 through August 2008, (ii) President and CEO of ETHEX from August 2008 through December 5, 2008, and (iii) CEO of the Company from December 5, 2008 through the end of the Class Period. By virtue of each of these positions Defendant Van Vliet was an executive officer of the Company and had direct involvement in the day-to-day operations of the Company, including discussions and meetings with FDA; and

(b) The FDA Complaint seeking to enjoin and restrain the Company from manufacturing and distributing pharmaceutical products named Defendant Van Vliet as a defendant precisely because Defendant Van Vliet had control of the Company and the power to have the Company manufacture and distribute pharmaceutical products.

224. Defendant Bleser exercised control of KV from April 2007 through the end of the Class Period for the following reasons:

(a) Defendant Bleser has been President of the Pharmaceutical Manufacturing Division since April 2007, and had direct involvement in the day-to-day operations of the Company, particularly with respect to manufacturing issues and discussions and meetings with FDA; and

(b) The FDA Complaint seeking to enjoin and restrain the Company from manufacturing and distributing pharmaceutical products named Defendant Bleser as a defendant precisely because Defendant Bleser had control of the Company and the power to have the Company manufacture and distribute pharmaceutical products.

225. As a result of the false and misleading statements and omissions alleged herein, the market price of KV securities was artificially inflated during the Class Period. Under such circumstances, the presumption of reliance available under the "fraud on the market" theory applies, as more particularly set forth above. Lead Plaintiffs and the other members of the Class relied upon either the integrity of the market in purchasing KV securities at artificially inflated prices or the false and misleading statements alleged herein.

226. As a direct and proximate result of Defendants Hermelin's, Van Vliet's and Bleser's wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their purchases of KV securities during the Class Period. Had Lead Plaintiffs and the other members of the Class known of the material adverse information not disclosed by Defendants, or been aware of the truth behind their material misstatements, they would not have purchased the securities at artificially inflated prices.

227. This claim was brought within two years after discovery of this fraud and within five years of the making of the statements alleged herein to be materially false and misleading and of the occurrence of the conduct alleged herein to violate Section 10(b) and Rule 10b-5.

228. By virtue of the foregoing, Defendants Hermelin, Van Vliet and Bleser are liable to Lead Plaintiffs and the Class, each of whom has been damaged as a result of the Company's underlying violations.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs pray for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;

B. Awarding Lead Plaintiffs and the members of the Class damages and interest;

C. Awarding Lead Plaintiffs' reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: March 18, 2010

Respectfully submitted,

/s/ Javier Bleichmar

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On Behalf of Lead Plaintiffs

AMENDED CERTIFICATION

I, Kathleen Kiely-Becchetti, as Interim Executive Officer of Boston Retirement Board, hereby certify as follows:

1. I am fully authorized to enter into and execute this Amended Certification on behalf of the State-Boston Retirement System ("Boston"). I have reviewed the Consolidated Amended Complaint prepared against KV Pharmaceutical Company ("KV Pharmaceutical") alleging violations of the federal securities laws;

2. Boston did not purchase securities of KV Pharmaceutical at the direction of counsel or in order to participate in any private action under the federal securities laws;

3. Boston is willing to serve as a lead plaintiff in this matter, including providing testimony at deposition and trial, if necessary;

4. Boston's transactions in KV Pharmaceutical during the class period are reflected in Exhibit A, attached hereto;

5. Boston sought to serve as a lead plaintiff in the following class actions under the federal securities laws during the last three years:

Garber v. Juniper Networks, Inc.
In re SafeNet, Inc. Securities Litigation
Ellen Rosenthal Brodsky v. Yahoo! Inc. et al,
In re Luminent Mortgage Capital, Inc., Securities Litigation
Briarwood Investments, Inc. v. Care Investment Trust, Inc.
Steinberg v. Ericsson LM Telephone Co.
Hubbard v. BankAtlantic Bancorp, Inc. et al
Joel Stratte-McClure v. Gary G. Lynch
Rubin v. MF Global, Ltd. et al
Genovese v. Ashley, et al
Iron Workers Local No. 25 Pension Fund v. Oshkosh Corporation, et al
Attias v. Anadigics, Inc. et al
Mas v. KV Pharmaceutical Company et al
In re Colonial Bancgroup, Inc. Securities Litigation

6. Boston is currently serving as a lead plaintiff in the following class actions filed under the federal securities laws during the last three years:

In re SafeNet, Inc. Securities Litigation
Hubbard v. BankAtlantic Bancorp, Inc. et al
Joel Stratte-McClure v. Gary G. Lynch
Rubin v. MF Global, Ltd. et al
Genovese v. Ashley, et al
Iron Workers Local No. 25 Pension Fund v. Oshkosh Corporation, et al
Mas v. KV Pharmaceutical Company et al
In re Colonial Bancgroup, Inc. Securities Litigation
Attias v. Anadigics, Inc. et al (pending)

7. Beyond its pro rata share of any recovery, Boston will not accept payment for serving as a lead plaintiff on behalf of the class, except the reimbursement of such reasonable costs and expenses (including lost wages) as ordered or approved by the Court.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct this 21 day of May, 2009.

KKB

Kathleen Kiely-Becchetti
Interim Executive Officer of Boston Retirement Board

EXHIBIT A

TRANSACTIONS IN KV PHARMACEUTICAL COMPANY

Transaction Type	Trade Date	Shares	Price Per Share	Cost/ Proceeds
Purchase	07/27/07	18,970.00	$ 27.16	($516,306.49)
Purchase	08/28/07	1,700.00	$ 26.77	($45,577.34)
Purchase	08/29/07	2,100.00	$ 26.75	($56,260.68)
Purchase	09/07/07	400.00	$ 27.05	($10,834.96)
Purchase	09/10/07	100.00	$ 27.00	($2,704.00)
Purchase	01/18/08	2,300.00	$ 27.94	($64,343.65)
Purchase	01/22/08	2,000.00	$ 27.82	($55,721.80)
Purchase	04/16/08	2,800.00	$ 25.37	($71,141.84)
Purchase	04/16/08	3,500.00	$ 25.46	($89,257.00)
Purchase	04/17/08	1,100.00	$ 25.27	($27,843.75)
Sale	01/15/09	-15,370.00	$ 2.32	$35,733.71
Sale	01/16/09	-3,720.00	$ 2.46	$9,166.82
Sale	01/16/09	-11,200.00	$ 2.44	$27,274.24
Sale	01/20/09	-920.00	$ 2.41	$2,212.60
Sale	01/20/09	-1,260.00	$ 2.43	$3,056.51
Sale	01/21/09	-2,500.00	$ 2.34	$5,861.00

AMENDED CERTIFICATION

I, Joseph Connolly, as Treasurer of Norfolk County Retirement System ("Norfolk County"), hereby certify as follows:

1. I am fully authorized to enter into and execute this Amended Certification on behalf of Norfolk County. I have reviewed the Consolidated Amended Complaint prepared against KV Pharmaceutical Company ("KV Pharmaceutical") alleging violations of the federal securities laws;

2. Norfolk County did not purchase securities of KV Pharmaceutical at the direction of counsel or in order to participate in any private action under the federal securities laws;

3. Norfolk County is willing to serve as a lead plaintiff in this matter, including providing testimony at deposition and trial, if necessary;

4. Norfolk County's transactions in KV Pharmaceutical during the class period are reflected in Exhibit A, attached hereto;

5. Norfolk County sought to serve as a lead plaintiff in the following class actions under the federal securities laws during the last three years preceding the date of this certification:

In re Herley Industries Inc. Securities Litigation
City of Brockton Retirement System v. The Shaw Group, Inc.
In re Luminent Mortgage Capital, Inc. Securities Litigation
Briarwood Investments, Inc. et al v. Care Investment Trust Inc.
Norfolk County Retirement System et al v. Ustian et al
City of St. Clair Shores Police and Fire Retirement System v. Gildan Activewear Inc. et al
Norfolk County Retirement System v. Harris Stratex Networks, Inc.
Joseph Mas v. KV Pharmaceutical Company et al
In re Colonial Bancgroup, Inc. Securities Litigation

6. Norfolk County is currently serving as a lead plaintiff in the following class actions filed under the federal securities laws during the last three years:

Briarwood Investments, Inc. et al v. Care Investment Trust Inc.
Norfolk County Retirement System et al v. Ustian et al
City of St. Clair Shores Police and Fire Retirement System v. Gildan Activewear Inc. et al
Joseph Mas v. KV Pharmaceutical Company et al

7. Beyond its pro rata share of any recovery, Norfolk County will not accept payment for serving as a lead plaintiff on behalf of the class, except the reimbursement of such reasonable costs and expenses including lost wages as ordered or approved by the Court.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct this 19 day of May, 2009.

Joseph Connolly
Treasurer of Norfolk County Retirement System

EXHIBIT A

TRANSACTIONS IN KV PHARMACEUTICAL COMPANY

Transaction Type	Trade Date	Shares	Price Per Share	Cost/ Proceeds
Purchase	07/24/06	1,900.00	$ 17.10	($32,537.31)
Purchase	07/24/06	4,300.00	$ 17.39	($74,915.46)
Purchase	07/25/06	100.00	$ 17.82	($1,785.29)
Purchase	07/26/06	200.00	$ 17.85	($3,575.28)
Purchase	07/27/06	600.00	$ 18.64	($11,202.00)
Purchase	08/28/07	400.00	$ 26.77	($10,724.08)
Purchase	08/29/07	500.00	$ 26.75	($13,395.40)
Purchase	09/07/07	100.00	$ 27.05	($2,708.74)
Purchase	01/18/08	800.00	$ 27.94	($22,380.00)
Purchase	01/22/08	700.00	$ 27.82	($19,503.00)
Purchase	04/16/08	1,000.00	$ 25.37	($25,407.80)
Purchase	04/16/08	1,200.00	$ 25.46	($30,602.40)
Purchase	04/17/08	300.00	$ 25.27	($7,593.75)
Purchase	05/30/08	2,256.00	$ 25.01	($56,467.68)
Sale	06/12/08	-886.00	$ 20.29	$17,941.31
Sale	06/13/08	-1,014.00	$ 19.80	$20,034.20
Sale	06/25/08	-356.00	$ 19.50	$6,927.72
Sale	09/23/08	-1,050.00	$ 23.52	$24,685.00
Sale	01/15/09	-4,860.00	$ 2.32	$11,177.00
Sale	01/16/09	-1,170.00	$ 2.46	$2,854.00
Sale	01/16/09	-3,540.00	$ 2.44	$8,585.00
Sale	01/20/09	-290.00	$ 2.41	$695.00
Sale	01/20/09	-400.00	$ 2.43	$960.00
Sale	01/21/09	-790.00	$ 2.34	$1,832.00

Exhibit 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. KV PHARMACEUTICAL COMPANY, ETHEX CORPORATION, and THER-RX CORPORATION; corporations, and DAVID A. VAN VLIET, MARC S. HERMELIN, RITA E. BLESER, and JAY S. SAWARDEKER, individuals, Defendants.	)	Case No.

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Honorable Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("the Act") 21 U.S.C. § 332(a), to permanently enjoin the corporate Defendants KV Pharmaceutical Company, ETHEX Corporation, and Ther-Rx Corporation (hereafter, collectively, "KV"), and the individual Defendants David A. Van Vliet, Marc S. Hermelin, Rita E. Bleser, and Jay S. Sawardeker (collectively, "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that the methods used in, or the facilities and controls used for their manufacture, processing, packing, labeling and holding do not conform to or are not operated and administered in conformity with current Good Manufacturing Practice

("CGMP") to assure that such drugs meet the requirements of the Act as to safety and have the identity and strength, and meet the quality and purity characteristics, which they purport and are represented to possess; (b) violating 21 U.S.C. § 331(k) by causing articles of drug, as defined by 21 U.S.C. § 321(g), that Defendants hold for sale after shipment of one or more of the articles' components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (c) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); (d) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and (e) violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and over all parties to this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant KV Pharmaceutical Company is incorporated under the laws of the State of Delaware, and has multiple locations in St. Louis, Missouri, and the surrounding area, with its corporate headquarters located at 2503 South Hanley Road, St. Louis, Missouri. Defendant KV Pharmaceutical Company is engaged in the business of manufacturing, processing, packing, labeling, holding, and distributing prescription and non-prescription drugs at its various facilities. KV Pharmaceutical Company distributes drugs under the ETHEX and Ther-Rx Corporation labels.

5. Defendant ETHEX Corporation, a wholly owned subsidiary of Defendant KV Pharmaceutical Company, is incorporated under the laws of the State of Missouri and its corporate office is located at One Corporate Woods Drive, in St. Louis, Missouri. Defendant ETHEX Corporation is engaged in the business of marketing and distributing drugs, including drugs manufactured by Defendant KV Pharmaceutical Company. Defendant ETHEX Corporation may have more than one location; however, all locations are in the St. Louis area and within the jurisdiction of this Court.

6. Defendant Ther-Rx Corporation, a wholly owned subsidiary of Defendant KV Pharmaceutical Company, is incorporated under the laws of the State of Missouri, and its corporate office is located at One Corporate Woods Drive, in St. Louis, Missouri. Defendant Ther-Rx Corporation is engaged in the business of marketing and distributing drugs, including drugs manufactured by KV Pharmaceutical Company. Defendant Ther-Rx Corporation may have more than one location; however, all locations are in the St. Louis area and within the jurisdiction of this Court.

7. Defendant David A. Van Vliet is currently the Corporate President and interim Chief Executive Officer of KV Pharmaceutical Company. He has served as the interim Chief Executive Officer since approximately December 2008. Prior to December 2008, he served as the President and Chief Executive Officer of ETHEX Corporation, the largest subsidiary of KV Pharmaceutical Company. Defendant Van Vliet is responsible for and has authority over all operations of KV Pharmaceutical Company including, but not limited to, the manufacture, processing, packing, labeling, holding, and distribution of drugs. He has the authority to order the recall of any drugs and to make changes in company procedures, including but not limited to manufacturing, laboratory, and quality control procedures. He performs his duties primarily at 2503 South Hanley Road, St. Louis, Missouri, within the jurisdiction of this Court.

8. Defendant Rita E. Bleser is the President of KV Pharmaceutical Company's Pharmaceutical Division. She has overall responsibility for the manufacturing and production

departments. She has the authority to make changes in manufacturing processes and the responsibility and authority to prevent and correct CGMP deficiencies at all production sites. She performs her duties primarily at 2503 South Hanley Road, St. Louis, Missouri, within the jurisdiction of this Court.

9. Defendant Jay S. Sawardeker is the Vice President of Corporate Quality for KV Pharmaceutical Company. He is responsible for quality compliance at all of KV Pharmaceutical Company's facilities. Defendant Sawardeker has responsibility and authority over product quality issues, he makes decisions regarding product recalls, product remediation, and rejection, and he has the authority to release or quarantine drugs. He performs his duties primarily at 2503 South Hanley Road, St. Louis, Missouri, within the jurisdiction of this Court.

10. Defendant Marc S. Hermelin served as Vice Chairman of the Board of Directors and Chief Executive Officer of KV Pharmaceutical Company from 1975 until August 2006. In August 2006, Defendant Hermelin became Chairman of the Board of Directors, in addition to Chief Executive Officer, and continued in both positions until December 5, 2008. In his capacity as Chief Executive Officer, Defendant Hermelin was responsible for and had authority over all operations of KV Pharmaceutical Company including, but not limited to, the manufacture, processing, packing, labeling, holding, and distribution of drugs. He had the authority to order the recall of any drugs and to make changes in company procedures, including but not limited to manufacturing, laboratory, and quality control procedures. Defendant Hermelin currently is a member on KV Pharmaceutical Company's Board of Directors in St. Louis, Missouri.

11. Defendants have been, and are now engaged, at their facilities in St. Louis, Missouri and the surrounding area, in manufacturing, processing, testing, packing, labeling, holding, and distributing in interstate commerce articles of drug within the meaning of 21 U.S.C. § 321(g)(1).

12. Defendants manufacture drugs using components they receive in interstate commerce and introduce finished drug products into interstate commerce for shipment outside the state of Missouri.

ADULTERATED DRUGS

13. The United States Food and Drug Administration's ("FDA") inspections of Defendant KV Pharmaceutical Company's facilities have established that the drugs manufactured by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, labeling, holding, and distribution of KV drugs and components are not in compliance with CGMP. See 21 U.S.C. § 351 (a)(2)(B); 21 C.F.R. Parts 210 and 211.

14. FDA's CGMP regulations require manufacturers to control the processes and procedures by which drugs are manufactured, processed, packed, and held in order to ensure that drug products have the identity, strength, quality, purity, and other attributes necessary for their safe and effective use. FDA regulations, which establish minimum CGMP requirements applicable to human drugs, 21 C.F.R. §§ 210, 211, require manufacturers to control all aspects of the processes and procedures by which drugs are manufactured to prevent production of unsafe and ineffective products. Drugs not manufactured, processed, packed, or held in conformance with CGMP are deemed adulterated as a matter of law, without the showing of actual defect.

15. During FDA's most recent inspection of Defendant KV's facilities between December 15, 2008 and February 2, 2009 (the "February 2009 inspection"), FDA investigators documented thirty-five (35) separate deviations from CGMP. These CGMP violations include, but are not limited to, the following:

A. Failure to follow the responsibilities and procedures applicable to the quality control unit, as required by 21 C.F.R. § 211.22(d);

B. Failure to establish control procedures to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product, as required by 21 C.F.R. § 211.110(a);

C. Failure to make written records of investigations into unexplained discrepancies and the failure to make written records of investigations of a batch or any of its components to meet specifications, as required by 21 C.F.R. § 211.192;

D. Failure to review and approve drug product production and control records by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed, as required by 21 C.F.R. § 211.192;

E. Failure to review and approve changes to written procedures by the quality control unit, as required by 21 C.F.R. § 211.100(a);

F. Failure to clean, maintain, and sanitize equipment and utensils at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product, as required by 21 C.F.R. § 211.67(a); and

G. Failure to follow written production and process control procedures in the execution of production and process control functions, as required by 21 C.F.R. § 211.100(b).

16. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth above.

17. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

UNAPPROVED NEW DRUGS

18. FDA's February 2009 inspection revealed that certain of the drugs manufactured and distributed by Defendants lack approved new drug applications ("NDAs") or approved

abbreviated new drug applications ("ANDAs"), as required by 21 U.S.C. § 355, and are not exempt under 21 U.S.C. § 355(i) from the Act's pre-market approval requirements. As a result, these drugs are unapproved new drugs within the meaning of 21 U.S.C. § 355(a).

19. Defendants violate 21 U.S.C. § 331(d) by introducing or causing to be introduced into interstate commerce unapproved new drugs.

MISBRANDED DRUGS

20. FDA's February 2009 inspection also revealed that certain of Defendants' drugs are misbranded because they are unapproved new drugs and they lack scientific evidence to demonstrate that they are safe and effective as indicated in their directions for use. Such drugs do not bear adequate directions for use as required by 21 U.S.C. § 352(f)(1), and they are not exempt from this requirement pursuant to 21 C.F.R. §§ 201.115 or 201.100. A prescription new drug is exempt from the adequate directions for use requirement only if it bears the precise labeling approved in its ANDA/NDA. Thus, any prescription new drug that lacks an approved NDA cannot satisfy this condition for exemption from the adequate directions for use requirement, and therefore is misbranded until such time as its ANDA/NDA is approved by FDA.

21. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), as set forth above.

22. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the misbranding, within the meaning of 21 U.S.C. § 352(f)(1), of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

PRIOR NOTICE TO DEFENDANTS

23. Defendant KV Pharmaceutical Company has a history of continuing CGMP violations. The deficiencies observed by FDA at the most recent inspection in February 2009,

are the same as, or similar to, prior violations observed by FDA at several other inspections conducted during the last eight years.

24. Defendant's noncompliance has continued despite repeated warnings from FDA regarding its CGMP violations. At the conclusion of each FDA inspection in 4/2003, 1/2004, 1/2005, 3/2006, 4/2007, 3/2008, 8/2008, and 2/2009, FDA investigators prepared and issued a detailed List of Inspectional Observations, Form FDA-483, to Defendants, notifying them of the investigators' observations. The FDA investigators discussed the violations listed in the Form FDA-483s with Defendants, who expressed a desire to correct the deficiencies. Nevertheless, FDA investigators have continued to observe CGMP violations at subsequent inspections.

25. FDA also issued a Warning Letter to Defendant KV Pharmaceutical Company on May 9, 2000, identifying numerous CGMP violations found during the February/March 2000 inspection. The Warning Letter emphasized the serious nature of the CGMP violations at Defendant KV and stated that a failure to correct the violations could lead to regulatory action, including seizure and/or injunction.

26. On October 11, 2002, FDA issued a Warning Letter to Defendant KV Pharmaceutical Company for marketing unapproved new drugs in violation of 21 U.S.C. § 355.

27. Plaintiff is informed and believes that, unless restrained by this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (d), and (k), in the manner alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants KV Pharmaceutical Company, ETHEX Corporation, and Ther-Rx Corporation, and David A.Van Vliet, Marc S. Hermelin, Rita E. Bleser, and Jay S. Sawardeker, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them from manufacturing, processing, packing, labeling, holding, or distributing any article of drug, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of drug are

established, operated, and administered in conformity with CGMP and the Act, in a manner that has been found acceptable by FDA; and

II. Permanently restrain and enjoin the Defendants KV Pharmaceutical Company, ETHEX Corporation, and Ther-Rx Corporation, and David A.Van Vliet, Marc S. Hermelin, Rita E. Bleser, and Jay S. Sawardeker, and each and all of their officers, agents, employees, successors or assigns, representatives, and attorneys, and any and all persons in active concert or participation with any of them, or any of them, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of § 352(f)(1);

D. Violating 21 U.S.C. § 331(k) by causing drugs that defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i); and

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the

injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and other such relief as the Court deems just and proper.

DATED this 2nd day of March, 2009.

Respectfully submitted,

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